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Maintaining physical readiness to meet demands of combat conditions is of utmost importance for active duty military personnel. As growing numbers of women of childbearing age enter active duty military service, the numbers of pregnancies among female military personnel will also increase. Thus, understanding the impact of pregnancy on subsequent fitness of postpartum active duty women becomes imperative. This project will describe the pattern of maternal weight loss after delivery in a large group of active duty and military dependent women, compare differences in weight loss by maternal characteristics, and identify characteristics of women who are most likely to become permanently overweight or obese as a result of childbearing. The study group will include 3000 women who bring their infants for pediatric care at the Naval Medical Center, San Diego. Postpartum weight will be measured at intervals ranging from 3 days to 12 months after birth. Data on prenatal factors, lifestyle behaviors, physical activity, work and other maternal characteristics will be collected by questionnaire and through abstraction of medical records. Analysis of these data will provide scientific evidence on which to base weight standards for postpartum active duty women.

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FOREWORD

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Barbara Abrams 11/13/98

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TABLE OF CONTENTS

Postpartum Maternal Weight Changes: Implications for Military Women

INTRODUCTION

Maintaining physical readiness to meet demands of combat conditions is of utmost importance for active duty military personnel. All branches of the military assess body size as a major indicator of fitness. During the last 20 years, the number of women on active duty in all services increased almost five-fold, from 2.5% in 1973 to 11.5% in 1992. As growing numbers of women of childbearing age enter active duty military service, the numbers of pregnancies among female military personnel will also increase. Thus, understanding the impact of pregnancy on subsequent fitness of postpartum active duty women becomes imperative.

During an average successful human pregnancy, the mother increases her body weight by 20% or more. There is strong and consistent scientific evidence that this weight gain plays an important role in ensuring a healthy infant. However, relatively few studies have addressed maternal weight loss after delivery and none have been conducted in populations of military women. Nonetheless, military women are required to return to active duty 6 weeks after delivery, in good physical condition and in uniform. Although studies in civilian populations suggest that it may take as long as a year to return to prepregnant body size,(1, 2) women in the military are expected to achieve weight and fitness standards much sooner than this: in the Navy and Marine Corps they are required to achieve weight and fitness standards within 6 months after delivery; the Army exempts women from standards for "the period of convalescent leave after birth," and the Air Force expects compliance by 3 months after delivery. Rehabilitation (comprised of a low fat diet and exercise regime) is required of women who fail to meet these standards, and if women remain outside acceptable ranges, they are subject to discipline or dismissal.

Yet, despite a body of previous research, the "normal" pattern of postpartum weight gain and risk factors for postpartum weight retention remain poorly understood. Without a clear understanding of the cause of weight retention, it is impossible to design effective strategies for intervention.

Background

Maternal weight retention after birth A 1990 Institute of Medicine (IOM) report concluded that, after considering weight increases due to age and given an average maternal weight gain during pregnancy, average permanent weight retention is about 1 kg per pregnancy.(5) Recent studies are consistent with this estimate, reporting the average mother retains about 1.5 kg (3.3 pounds) of her pregnancy weight gain(1,2,6), although several report values as high as 3.8 kg (8.4 lb) at one year postpartum.(7,8) A comparison of 18-30 year old women who had been pregnant with those who had not over a 5 year period concluded that primaparas gained, on average, 2-3 kg more weight than nulliparas.(9)

However, focusing on the average weight retention can obscure important differences in subgroups. For example, median weight retention at 10-18 months after delivery was only 3.4 lb in the 1988 National Maternal Infant Health Survey (NMIHS), a national sample of 2845 US.

women, but 25% of white women and 40% of black women retained more than 9 lb.(6) Similarly, in a study of 1423 Swedish women, after controlling for weight change with age, average weight retention at 1 year postpartum was only 0.5 kg(1 lb) but the frequency of overweight women increased from 13% before pregnancy to 21% postpartum.(1) Thus, studies of maternal weight retention must assess not only the experience of average women, but also provide information on subgroups, for example, by race, prepregnant size, or breast feeding status.

Pattern of postpartum weight loss Because of fluid adjustments that occur immediately after birth, most women lose weight quickly until two weeks postpartum, and then the rate of weight loss levels off.(5) Among mostly middle class white mothers who delivered in Wisconsin, fewer than one-fourth had returned to their pre-pregnancy weights by 6 weeks postpartum,(2) and mean weight retention at 6 weeks was 4.5 kg in 400 Illinois women.(8) Furthermore, in the Wisconsin study, only 37% of the women had returned to their prepregnancy weight by 6 months after delivery. These data indicate that maternal weight is not lost immediately after pregnancy, and additional research is needed to describe both average loss and its distribution throughout the first year after delivery.

Predictors of postpartum weight loss

Prenatal weight gain The strongest factor contributing to weight changes postpartum is prenatal weight gain.(1,2,5,6,8,10-13) For example, our multivariate study of the 1988 NMIHS found that women with normal prepregnancy body size who gained above 35 pounds (the upper limit of the current IOM recommendation for prenatal weight gain in normal weight women) were over twice as likely to retain 20 or more pounds postpartum than those who gained within the IOM guideline of 25-35 pounds.(11) This increased risk was present for both white and black mothers and persisted after adjustment for various maternal characteristics. Postpartum weight retention in this population was relatively low among white mothers who gained within the IOM recommendation, suggesting that current prenatal weight gain guidelines may provide some protection against postpartum obesity for these women.(6,11)

Race Since black mothers, on average, gain less weight during pregnancy than white mothers,(5) one would expect that black mothers would retain less after delivery. However, data from the 1988 NMIHS survey indicate that black mothers retain on average more weight than white mothers.(6) This difference persists regardless of prepregnancy body size or prenatal weight gain. Furthermore, in our multivariate study of NMIHS participants with normal prepregnancy weight-for-height, black mothers were over twice as likely to retain 20 or more pounds postpartum than white mothers.(11) This difference remained after adjustment for maternal age, parity, prenatal weight gain, infant birth weight, height, prepregnancy body size, marital status, and social class. Other recent studies reported similar findings.(9,13) We have identified no published data on postpartum weight change in mothers who were Hispanic, Asian or other races. Additional research is clearly needed to determine factors that influence maternal weight loss after delivery by race.

Physical activity Increasing levels of physical activity is one of the hallmarks of weight management, but little is known about the impact of recreational or occupational physical

activity in relation to maternal weight loss after delivery.(13) In a Swedish study, women who retained excess weight postpartum reported low levels of recreational physical activity during the year after birth, and increased physical activity was correlated significantly with postpartum weight loss.(14) In another small study of exclusively breast feeding women, maternal weight loss did not differ for mothers who undertook regular aerobic exercise between 6 and 18 weeks postpartum, compared to those who did not, although exercising mothers became more physically fit than their non-exercising counterparts.(15)

Dieting Not much is known about the impact of dieting during the postpartum period, for either lactating or non-lactating mothers.(14) Results of a study of Swedish women suggested that intentional dieting was associated with increased weight loss, while certain dietary practices (e.g., increased meal size, increased snacking, meal skipping) were associated with excessive weight retention.(15) Dieting is of special concern to women who breast feed, because while there appears to be little or no relationship between moderate changes in energy intake and milk volume, there is some evidence that a threshold exists under which the quality and quantity of breast milk may be compromised.(14)

Cigarette smoking Cigarette smoking, which is a major risk factor for poor health in general and during pregnancy, is protective against excessive weight retention postpartum.(1,2) In fact, the highest risk of weight retention may occur in mothers who quit smoking during pregnancy and do not resume postpartum.(1) This observed benefit of smoking does not offset the toxic effects of cigarettes on the health of both the mother and her baby.

Breast feeding New mothers are commonly told that breast feeding will accelerate their weight loss after birth. The basis of this advice is the assumption that fat stores gained during pregnancy are mobilized to subsidize the energy cost of lactating. However, while some studies suggest that breast feeding women lose weight faster than bottle-feeding women, many do not.(2,3,8,10,11,16-18)

Prepregnancy body size and weight history Wider variations in weight change postpartum are observed in women who begin pregnancy overweight than in lighter women.(1,10) There is also evidence that women with a history of weight cycling and dieting are more likely to retain excessive amounts of weight after pregnancy.(1, 19)

Social factors There is consistent evidence that women with lower income and lower education may have an increased risk of retaining more weight postpartum than women with higher socioeconomic indicators.(8,11) It is likely that socioeconomic differences are based on lifestyle behaviors and environmental circumstances. Other important risk factors for excessive postpartum weight retention include maternal age, parity, interpartum interval and maternal work outside the home. For these variables, study results are not consistent, suggesting the need for additional research.(20) Furthermore, the importance of adequate help and social support during the year after delivery to maternal weight changes, especially for those mothers working outside the home, has not been studied.

Gestational weight gain, fetal outcome and maternal postpartum weight retention As previously discussed, maternal weight gain during pregnancy is an important risk factor for

excessive postpartum weight retention. This implies that restriction of maternal weight gain during pregnancy might be a useful strategy to promote a quicker maternal postpartum weight loss. However, maternal weight gain during pregnancy is an important determinant of fetal size at delivery, which in turn is the most important predictor of survival and health of the newborn.(5) Reflecting this relationship, current recommendations for maternal weight gain during pregnancy are higher than ever before, especially for women who begin pregnancy at or below ideal weight for height.(5) Thus, although the major focus of this study is maternal weight after delivery, the birth weight of the infant must also be considered.(21) Furthermore, the pattern of maternal weight gain during pregnancy may play a more important role in fetal outcome than the total amount, although only a few studies have examined this issue. We have recently published a multivariate analysis of almost 3000 white women which suggests that, even when total maternal weight gain at delivery is held constant, a low maternal weight gain during the second trimester is associated with a significantly smaller infant.(22) Thus, maternal weight gain pattern appears to relate to infant birth weight, and it is also likely that the pattern of maternal weight gain may relate to postpartum weight retention. Several epidemiological studies have attempted to quantify levels of maternal gestational weight gain that promote fetal weight while reducing excessive maternal weight retention after delivery. One study concluded that for women who gain excessively, there is a "point of diminishing returns in birthweight at the expense of increasing maternal obesity."(23) Another concluded that "excessive gestational weight gain before 20 weeks gestation was associated with increased postpartum weight retention, especially for well nourished, overweight women."(24) A third study concluded that, in women with normal prepregnancy weight, excessive gestational weight gain did not greatly enhance fetal growth but did increase the risk of postpartum overweight.(12) However, none of these studies were able to examine factors related to maternal weight gain during pregnancy or behavioral predictors of maternal postpartum weight.

Study objective

This project, "Postpartum Weight Changes: Implications for Military Women" is referred to in the rest of this report as the "ABC Study". It addresses the question "how long to allow for returning to weight and physical fitness that meet service standards" found on page 39 of the Institute of Medicine's 1995 report Recommendations for Research on the Health of Military Women. The same issue falls under Physical Standards Linked to Occupations, "The scientific basis for physical standards" on page I-6 of the September 15, 1995 Broad Agency Announcement for Defense Women's Health Research.

The major objectives of the study are to:

1) describe the pattern of weight loss during the first year after delivery in a large study group of active duty and military dependent women,
2) compare differences in weight loss by maternal characteristics, and
3) identify characteristics of women who are most likely to become permanently overweight or obese as a result of childbearing.

These study results will contribute to the development of data-based standards which reflect the experiences of women who will return to acceptable levels of weight and fitness on their own, and thus could reduce the number of women who require formal rehabilitation, and the possible

stresses that it may impose. Information on common predictors of excessive and permanent weight retention could allow earlier identification of women at risk, with the potential for prevention, for example by encouraging an appropriate diet and increased levels of physical activity during pregnancy or earlier after delivery. Because obesity increases the risk of overall mortality and morbidity from serious medical conditions such as cardiovascular disease, diabetes, hypertension, and some forms of cancer (3, 4), addressing weight loss postpartum will be important for the long term health of the career service women as well as for military dependents.

Overview of Study Design

The study has 2 components: a series of cross-sectional slices at 3 days, 14 days, 2,4,6,9 and 12 months, and a smaller longitudinal cohort. Some women in the study provide data at only one or two points of time (for example if enrolling at the end of the first postpartum year, or if entering or leaving the facility due to transfer, deployment, or separation). We intentionally selected the sequential design to accommodate routine military operations by which personnel are transferred, on average, every 3 years. If we had utilized a strict prospective cohort design, we could automatically lose at least one-third of our cohort before completing follow-up. By defining our study groups according to infant age, data from women who are transferred can be utilized for the periods they participated, and new data from recent transfers can also be added to the study.

A basic question of this project is why a mother does or does not return to her prepregnancy weight during the postpartum period. The analysis of this type of failure data has a rich history. Or particular importance is the use of the Kaplan-Meier failure curves as a descriptive tool and the use of the proportional hazards model as an analytical tool. The proportional hazards model allows the evaluation of the influence of any number of factors on the risk of not returning to one's prepregnancy weight. Variables such as active duty status, physical activity, dieting practices, infant feeding, previous weight history, etc, are entered into the model as independent variables and the dependent variable is the time to losing sufficient weight to equal the reported prepregnancy weight. Mothers who fail to reach their prepregnancy weight by the end of the data collection period. Or those with missing data on weight are censored observations. The proportional hazards model accounts for these types of data losses producing unbiased estimates of the influence of the risk factors. Therefore, the Cox proportional hazard model will be the "workhorse" of the primary analyses for the ABC Study.

Previously published studies of postpartum women have relied almost exclusively on a volunteer study group. To reduce selection bias, we designed this study to be denominator-based, using as our sampling frame all well-baby appointments for infants 12 months or younger included in the Naval Medical Center's computerized appointment system. Our study Participant Tracking System communicates daily with the Navy system to estimate our study base and support the recruitment and follow-up process.

At enrollment, and at all subsequent study visits, maternal weight is measured and a questionnaire completed in the clinic. Additional take-home questionnaires are collected at baseline and at 12 months after birth. Weight measurements and questionnaire data are then

merged with information on pregnancy course and outcome abstracted from each participant's prenatal medical records and with data collected during the screening process. This final data set addresses the technical objectives of the project.

Our questionnaires are designed to provide a comprehensive assessment of the most likely factors related to postpartum weight retention. We are collecting data on maternal race/ethnicity, education, parity, postpartum lifestyle factors including physical activity, work, infant feeding practices and maternal dieting practices. In addition, we are assessing long-term weight history, attitudes and expectations about weight and body image, social support and stress, depression, and, for active duty women, Physical Readiness Training. We are looking carefully at how the prenatal experience relates to postpartum weight by collecting data on pre-pregnancy weight, prenatal weight gain, physical activity and dieting practices during pregnancy, and attitudes and information received relating to weight change in pregnancy and postpartum. To enhance the validity of our exposure assessment, our methods are relatively detailed and whenever possible, we use instruments that were previously validated in similar populations. We believe that this is the first study to simultaneously examine such a wide range of possible factors related to postpartum weight in such detail in so large a study population.

In creating our questionnaires, we focused on the practical implications of the research. We are collecting data on characteristics that could be easily measured in the clinical setting and also on factors that are potentially amenable to change. For example, we use a validated method to obtain detailed assessments of physical activity related to work, recreation and lifestyle. We also ask active duty women a series of questions about Physical Readiness Training. In addition to estimating each woman's physical activity, we also ask her to identify barriers to being physically active. Thus, if we find that lack of physical activity is associated with excessive weight retention, our results could be useful in planning interventions for military or civilian women.

Study Implementation

The ABC Study is successfully integrated into the Pediatrics Clinic at Balboa Hospital at the Naval Medical Center, San Diego (NMCSD). As of September 30, 1998, 2264 women have enrolled in the study. Five hundred twenty five (23%) are active duty and the remaining 1739 women are military dependents. At current accrual rates we expect to enroll 3000 women by the time we leave the field in March. The number of observations available will allow the study to meet most of its important scientific aims, especially given the scope and depth of the variables measured. Thus, compared to the original proposal, which aimed to enroll 4000 women, this large study is somewhat smaller in number, but richer in content. Use of multivariate models, such as the Cox Proportional Hazards model, is extremely efficient, requiring hundreds of observations, not thousands.

Recruitment

Our study office is located in the Pediatrics Clinic at the NMCSD. The study is constantly visible in the Pediatrics Clinic waiting and examination room through the use of flyers, brochures and posters. To be more attractive to our potential participants, we have

aggressively marketed the ABC Study. We gave the study non-technical name to increase its appeal to mothers: the "ABC Study", which stands for "After the Baby Comes". We created a special logo: a teddy bear wearing a sailor hat sitting with "ABC" blocks in the foreground. This logo appears on all study materials to increase study visibility. We have publicized the study at heath fairs, through articles appearing in various newspapers read by Navy Personnel, by a message posted on the hospital marquee and by messages included in the Plan of the Day.

To raise awareness of the study prior to the actual moment of recruitment, we collaborated with nurses in the prenatal setting to introduce the study to pregnant women in anticipation of their enrollment after delivery. Currently, the study is introduced to all women at the Prenatal Clinic at NMCSD as well as at the Active Duty Women's Prenatal Clinic at the 32nd Street Clinic at about 28 weeks gestation. Each woman is given a "crib card" for newborns which describes eligibility criteria and information on how to contact the study on one side and displays the study logo on the other. Last April we also began presentations (Monday through Friday) of the study to the discharge class required of all postpartum women leaving the hospital with newborn infants. These activities have facilitated enrollments as women have already heard about the study prior to arriving in the Pediatrics Clinic.

Field staff are employed and supervised by the study subcontractor, Freeman, Sullivan and Company (FSC). Our San Diego field supervisor, Rhonda Dittmar, R.N. is a pediatric nurse with extensive clinical experience at both the NMCSD clinic and hospital. She has served as field supervisor continuously since the study began, and her work is outstanding. Rhonda supervises recruiters, coordinates all project procedures with the clinic staff, represents the study to entire population of women and other employees at the NMCSD and serves as a bridge between clinic operations and data management at FSC and Berkeley.

In the clinic, study staff are readily identifiable by their ABC study lab coats and colorful identification tags. Our recruiters work on the study part-time. They have been extensively trained in study procedures and they have been integrated into the daily operations of the Pediatrics Clinic. Most of them are students in the health professions and each is enthusiastic about the study and excited about working with mothers of new babies

Recruiters draw from the sampling frame consisting of all well-baby appointments included in the NMCSD's computerized Composite Health Care System (CHCS) for infants less than or equal to 12 months old. The CHCS tracks all medical appointments and associated characteristics for all patients at the NMCSD. Our study Participant Tracking system communicates daily with the Navy system and supports the following activities.

On a day-to-day level, the Tracking System:

1) Identifies the underlying well-baby clinic population of mothers who serve as our sampling frame for each day, including information on the military sponsor, age of infant, and name/identification number for each mother-baby pair.
2) Produce a Master list for recruitment and follow-up.
3) Supports estimates of research staffing needs in the clinic for scheduling purposes.

The Tracking System monitors study progress by allowing us to:

4) Track the status, characteristics and progress of each of the study participants.
5) Assess our success in approaching, screening and enrolling of potential study participants.
6) Assess follow-up success.
7) Identify women that require additional follow-up by mail or phone.
8) At the end of the study, compare those who did enroll with those who did on age of infant and military status of the mother. These are the only two variables in the CHCS database that are complete and reliable enough to use for this comparison.
9) At the end of the study compare those we lost to follow-up with those who contributed data.

Each day, study staff print out a Master appointment list that identifies mothers with scheduled appointments. Unfortunately, this list is not a true sampling frame on the day of data collection, because it does not include about 20% of mothers with well baby visits that are scheduled at the last minute or booked into acute visit slots. Nonetheless, it provides an excellent starting point for recruitment and follow-up activities. Since the computerized list is not complete, our recruiters circulate throughout the clinic waiting room to ensure that they can describe the study and screen as many women with infants as possible. For women who enroll, the recruiter obtains informed consent and permission to obtain prenatal records, gathers questionnaire, weight, and height data from enrolled mothers, and explains future study procedures. Details on the recruitment procedure are available in Appendix A. The recruiters then account for every mother already on the appointment list and add those mothers that they encounter who were not on the list. This provides an accurate report of daily recruitment activities. This method of recruiting is somewhat more time consuming and requires more staff, than we originally envisioned, but it creates the most accurate sampling frame.

While our ABC study staff directly recruits and collects data, we also rely heavily on the Pediatrics clinic staff to answer questions about the study, encourage women to participate, and support study operations as described below. We have involved clinic personnel by providing individual orientations to staff members, and by presenting the study formally through presentations to the pediatrics and combined pediatrics/obstetrics staff conferences, and to meetings with clerical and corpsmen staff. Updates on the study are regularly communicated to keep Pediatric staff engaged in the process of encouraging mothers to participate in the ABC study and in supporting study operations.

Follow-up

The follow-up process for the enrolled participants depends on the same Participant Tracking System used for recruitment. Follow-up appointments are identified the day before through the Master appointment list (a "participant" code appears instead of a "not approached" code). Study staff insert study questionnaires in each infant's medical record. Participants are currently identified at check-in by neon ABC stickers affixed to the infant's medical record in case the participant does not identify herself. Actual follow-up is accomplished with the assistance of Navy clinic personnel, particularly the check-in clerks and the corpsmen, in conjunction with the ABC study staff. Check-in clerks have been trained to give each ABC participant the study questionnaire and an ABC sticker to wear. The stickers on the mother

informs the corpsmen to weigh the mother, record her weight on the back of the questionnaire, and remind her to complete the questionnaire and drop it in the ABC drop box or return it to study staff. The stickers also alert study staff that the woman is already a participant and therefore requires follow-up data collection rather than recruitment. Whenever study staff are not involved in recruitment, they are actively working with women to ensure that they complete their follow-up visits. Details on the follow-up procedures are found in the Appendix A, Page 25.

Take home questionnaires are currently provided, with a self-addressed, stamped envelope, to each mother when she appears for the appropriate follow-up visit. If the Take-home questionnaire is not returned, we routinely mail it to each participant up to three times. Participants are paid $10 each for returning the Baseline and Follow-up questionnaire.

Variables Studied

Data for this project are collected from 3 different sources: 1) Measurements of weight (and one height measurement) during clinic visits, 2) Clinic and Take-home Questionnaires, and 3) Medical Record Abstraction.

Weight and Height: Maternal postpartum weights are measured at each clinic visit on a calibrated, digital scale. The mother wears light clothing and no shoes. Each mother is weighed twice, and if the two weights disagree by more than 0.1 kg, the mother is weighed a third time. Maternal height is measured at the first visit using a stadiometer. At the first visit, we measure height at least twice to ensure accuracy. All enrollment measurements are currently collected by trained study staff while the majority of the follow-up measurements are taken by clinic corpsmen who have been formally trained to follow specific protocols. A quality assurance protocol is in place. A study staff member re-checks the accuracy of the each person taking measurements on a routine basis and then provides retraining as needed. At the request of our collaborating pediatricians, we are also recording and entering infant weight, length and head circumference at each visit.

Questionnaires

We collect data using the following questionnaires:

- 3-7 Day Clinic Questionnaire: A short questionnaire consisting of ~8 questions given only to mothers enrolled at the 3 day weight check. We intentionally kept this instrument brief to minimize participant burden.

- 10-16 Day Clinic Questionnaire: A slightly longer questionnaire (~30 questions) given only to mothers at the 2 week well-baby check.

- 2-12 Month Clinic Questionnaire: This questionnaire is self-administered at each well-baby or non-urgent care appointment beginning at 2 months postpartum . Although it consists of ~ 50 questions, most women easily complete it in about 10-15 minutes.

- The Baseline Questionnaire: This questionnaire is administered at home at 2 months postpartum or whenever the mother enrolls if here baby is older than 2 months of age. It

asks questions about family history, prenatal weight gain, smoking, physical activity, dieting practices and work during and after pregnancy and sociodemographic data. Depression and body image scales covering the previous seven days are also included. This questionnaire is lengthy and relatively demanding in scope.

- The Follow-up Questionnaire: This questionnaire is administered at home at 12 months postpartum. It asks women to reflect upon the past year in relation to their work, physical activity, dieting behavior and infant feeding practices, etc. It also includes a depression scale for the previous seven days. This questionnaire is lengthy and relatively demanding in scope.

- The 12 Month Enrollment Questionnaire is designed specifically for women who enroll at the 12 month visit. It replaces the Baseline and Follow-up Questionnaire by combining the most relevant questions from each. This questionnaire is also sent to women who enrolled earlier in the study, but never returned a baseline questionnaire. This questionnaire is lengthy and relatively demanding in scope. It is also administered at home.

Questionnaire Content

As cited in the background section, many studies have examined postpartum weight loss, but most have limited their explanatory variables to a few factors, such as maternal age, parity, race, infant feeding method and prenatal weight gain. In most of the studies, even these few variables have been measured in rather crude ways, leaving many questions about the nature of the relationships analyzed. A few have measured physical activity or work in a cursory way. To our knowledge, the only study to collect data on weight history and dieting practices was in Swedish women. Except for this Swedish study, we are aware of no large studies that have simultaneously addressed a large array of factors that may influence postpartum weight. Thus, a major strength of the ABC Study is its comprehensive assessment of a wide range of social, prenatal, psychological and lifestyle variables. The breadth and depth of the information we are collecting increases the potential that, unlike previous studies, when we find an association between a specific exposure and postpartum weight, we will be able to explain the relationship. Appendix B contains a copy of the 2-12 month Clinic and Baseline Take-home questionnaires (other questionnaires are available upon request). Whenever possible we have used validated instruments and standard definitions to be consistent with other studies. This approach is summarized below.

1) Depression: is measured using the Center for Epidemiologic Studies-Depression Scale (CES-D) because it has been validated in the scientific literature (25) and it has been used in other large recent studies of women (the National Institute of Aging's SWAN: Study of Women Across the Nation study, WIHS: Women's Interagency HIV Study, funded by several institutes within the National Institutes of Health, and the Centers for Disease Control's HERS: HIV Epidemiology Research Study). This instrument consists of 20 short questions that are easy to understand and it is easily self administered. We considered scales designed specifically to

measure postpartum depression, particularly the Edinborough Postnatal Depression Scale (26), but decided that the CES-D was a more useful assessment of mood for this population. We hypothesize that depression will be associated with excessive weight retention in some women and excessive weight loss in others.

2) Lactation: To measure intensity of lactation, we developed an infant feeding question for the clinic questionnaire. It is based upon the recommendations by the Institute of Medicine.(27) Our question differentiates between exclusive breast feeders, formula feeders and levels in between these extremes: partial and token breast feeders. Questions about other foods and juices fed to the baby are also included in the clinic questionnaire. To measure duration of breast feeding, we also included questions in the 12 Month Follow-up questionnaire to determine when mothers began to wean their infants and stopped breast feeding completely. We also investigate the barriers to breast feeding and the reasons women stop. The series of possible responses compiled from other studies (28) serve as the basis for this question.

3) Body Image: We conducted an extensive review of the literature addressing measurement of body image perceptions and identifying people with eating disorders. Because many of the questionnaires were outdated or extremely long and detailed, we chose to develop 4 very short questions about weight, shape, eating and appearance that generally measure the amount of time a mother thinks about these issues, using the same response categories in the CES-D (depression) scale.

We also chose to include a set of 9 silhouettes of women ranging from quite thin to very obese. These silhouettes have been validated in the literature (29) and have been used successful to measure body image of pregnant women.(30)

4) Dieting Practices: We compiled an extensive list of dieting practices based primarily upon questions utilized in the National Center for Health Statistics studies and other sources.(31,32)

5) Physical Activity: We worked very closely with our consultant exercise physiologist to develop a combination of validated scales to measure current overall activity and work-related activity.(33-38) These questions were then adapted to reflect recalled physical activity during pregnancy.

6) Active Duty Women: After meeting with active duty women (both postpartum mothers participating in our pre-tests and female pediatric staff), we developed a series of questions related to physical readiness test concerns and physical training requirements. These data should be useful in determining whether certain occupational practices, such as required PRT, are associated with more successful return to prepregnancy weight.

7) Social Support/Deployment/Spouses/Emotional Issues: We developed a series of questions to estimate social support because we did not identify a useful source of published questions after consulting with expert psychologists here at UCB. To our surprise, during the pretest, women universally stressed the importance of measuring spousal deployment as a potential factor in maternal postpartum weight. Therefore, we added questions to measure the

duration of paternal deployment during the baby's first year. We also have included questions on self-perceived stress and infant health problems as we suspect these factors may influence changes in maternal body weight.

7) Dietary Intake: The Health Habits and History Questionnaire (HHHQ-Block) is a semi-quantitative food frequency instrument developed and validated by Gladys Block at the National Cancer Institute and here at Berkeley. This self-administered questionnaire is highly respected and used in numerous studies throughout the United States to measure diet and health.(39) We included it to assess dietary intake during the 6-12 months postpartum period. However, this questionnaire is time consuming, and when we determined that the response rate to the Follow-up questionnaire was lower than expected, we removed the food frequency instrument. We intend to analyze the data for the more than 100 women who did complete it.

Medical Record Abstraction

The goal of medical record abstraction in the ABC Study is to collect information from the medical records of participants regarding their prenatal course and delivery. This information will:

1) Provide demographic data regarding the mother,
2) Allow calculation of the gestational age of the infant at the time of delivery,
3) Allow calculation of the total weight gain and pattern of weight gain during pregnancy for the mother and
4) Provide information regarding the type of delivery, complications, and birth weight of the infant(s).

We will use these data to examine the relationship between prenatal, labor and delivery factors and the health and fitness of mothers in the first year following the delivery. Please see Appendix C for a copy of the Medical Record Abstraction Form.

To obtain data from the prenatal records, mothers who delivered at Balboa Hospital sign a release form that meets the NMCSD institution's exact specifications. About 80% of our participants deliver at NMCSD. Mothers who delivered at other hospitals sign a different release form. After a mother enrolls, the forms are transferred to FSC in San Francisco, and evidence that she signed a medical release form is entered into the FSC Participant Tracking System. Specially trained staff in San Diego order the records from a list generated at UCB. They insert a copy of the release form into the record, abstract the data onto a standard form, and mail the completed data abstraction sheets to UCB where they are logged into the Participant Tracking System MRA database.

For records at other hospitals, we generate a letter requesting the record, include copies of each medical release form and track the progress of obtaining the record. The process for non-Balboa records is more complex, often requiring several contacts. Once the records arrive at Berkeley, data are abstracted onto our standard form by a trained staff.

The entire medical record abstraction process is managed by the MRA database at UCB which tracks the progress of ordering, obtaining and successfully abstracting each record. The coded Medical Record data are then sent to our outside vendor for key entry. All copies of medical records are currently stored in locked cabinets to preserve confidentiality, and all will be destroyed at the end of data collection. To date, we have key-entered 782 records.

Data Management,Tracking and Quality Control

Data Flow Each week ABC study enrollment packets for new participants, Screening Forms for all other women approached who did not enroll, and follow-up clinic questionnaires are mailed from San Diego to FSC at San Francisco. Data needed for tracking are entered into the FSC Participant Tracking System, described in Appendix D. In July, 1998, FSC also began tracking the process of mailing and handing out the take home questionnaires, allowing an assessment of the percent returned. This information has already allowed us to modify study operations to enhance the return of baseline and follow-up questionnaires.

Once logged into the system, the questionnaires are edited and organized into batches, coded and then sent to an outside vendor for data-entry. Specific processes for data editing and data entry are in place.

Quality Control of clinic operations is assured in several ways. A detailed manual of all study operations has been created. Field methods and questionnaires were pre-tested and revised before implementation. Each recruiter's performance in approaching, enrolling and following study participants is monitored by the nurse-supervisor using a specially-developed form which measures accuracy, procedural adherence, knowledge of the study, efficiency in time management, and recruiting techniques. The nurse supervisor is also responsible for formally training the corpsmen to correctly measure and record weight and height, and to assess the accuracy and reliability of these measurements on a regular basis.

Data coding and double keyed and verified data entry are preformed by trained personnel with procedures in place to assure data quality. All staff in San Diego, at FSC and at UCB have been formally trained, updates to protocols are implemented systematically and their impact is evaluated regularly. FSC communicates progress in the field to the Principal Investigator via a monthly report. There is daily communication by phone and email between FSC in San Francisco, UCB and the San Diego staff. UCB and FSC San Francisco staff also make monthly site visits to San Diego.

Medical record abstraction is verified by retrieving a randomly selected sample of medical charts and comparing the original data against entered data.

Data Analysis Data are analyzed by the research team at UCB. Once adequate data are available electronically, we will seek substantial input from the co-investigators at the NMCSD and from our Scientific Advisory Board which includes our clinician co-investigators at the NMCSD, an obstetrician and three nutritionists with expertise in energy balance, obesity and postpartum nutrition. The raw data will be entered into a database file and cleaned prior to analysis. The data analysis plan has not changed from that described in the original proposal, and will not be repeated here because our emphasis in this year has been to develop and implement study protocols to produce the highest quality data for analysis. With our field operations established and running smoothly, our focus is now shifting toward data analysis strategies in the coming year. We are currently processing our first shipment of entered data.

Preliminary Results

Study Population

Over the 16 months of data collection, we have encountered 11,407 of the 19,907 well baby visits that occurred at the Pediatrics Clinic at NMCSD. Thus, the overall study approach rate is close to 60%. However, this number reflects a very low approach rate (28%) during pilot phase of the study (from May, 1997 through October, 1997) due to a series of problems related to clinic operations, the study population and the electronic sampling frame described in both this and last year's annual report. After aggressively redesigning study procedures, we increased the approach rate to 72% of all baby visits from November through August 1998. During September 1998, we approached 76% of all well baby visits. The number of well baby visits reported here reflects repeat visits by individual mothers during the study period. As of September 30, 1998, approached 3556 of 5937 individual women.

Of the 3556 women we screened, approximately 20% (n=704) do not meet the study eligibility criteria. Sixty six percent of the ineligible women do not plan to obtain further well baby care at the Balboa Pediatrics Clinic. The remaining women are ineligible for the following reasons: the infant is older than 12 months (2%), the mother cannot read or speak English (6%), the child was in the neonatal intensive care unit longer than 96 hours (22%), the mother is currently pregnant (3%), and other reasons, such as the baby is adopted (1%). Of the remaining 2852 women we approach, a total of 588 (17%) are not screened for eligibility because they either ask to be approached at their next visit (n=250) or decline to participate in the study (n=338). Some of the women who ask to be approached later actually do enroll at a subsequent visit. Among women screened by September 1, 1998, 80% (n=2168) have enrolled in the ABC study.

As of September 30, 1998, 2264 (approximately 80% of all screened) women have enrolled in the ABC Study. Twenty three percent (n=525) are active duty and the remaining mothers (n=1739) are dependents of active duty servicemen. Only 52 of these women (including 19 active duty mothers) have quit the study due to pregnancy, leaving the area or for other reasons. Sixty four percent of the enrolled women are first time mothers; 25% have an older child, 8% already have 2 older children and only 3% of the study group have 3 or more additional children.

Forty five percent of the women are enrolled when their infants are between 3 and 16 days old, and 20% of the study group enrolled when their infants were 2 months old. Twelve percent of the mothers enroll when their babies are 4 months old and 10% are enrolled with 6-month old infants. Only 8% and 5% of study mothers initially enroll when their infants are 9-months old and 12-months old, respectively. Eighty percent of the infants in the study were delivered at Balboa Hospital at the NMCSD.

As of Sept 30, 1998, we have collected 5627 clinic questionnaires. We have collected 626 3-7 day questionnaires, 785 10-16 day questionnaires, 1123 2-month questionnaires, 973 4-month questionnaires, 912 6-month questionnaires, 681 9-month questionnaires and 537 12-month questionnaires. Follow-up of mothers in the clinic has improved markedly over time.

Our analysis of appointments that occurred through April, 1998 showed that we have obtained 78% of the ABC measures. This figure rose to 85% of all appointments through August, 1998 and for the babies born in 1998 and enrolled, we have obtained data on 93% of the follow-up visits.

The clinic questionnaires provide important information on exposures, but we also collect more detailed information using the take-home questionnaires. As of September 1, 1998, we have collected 1884 take home questionnaires: 1428 providing baseline data (71% of all enrolled women) and 456 providing follow-up data (50% of all women with 12 month-old infants). This includes the 90 12-month enrollment questionnaires that combine data from the baseline and follow-up questionnaires. We expect that the strategies now in place will continue to enhance the return of these questionnaires.

Preliminary Findings

Although we have collected baseline questionnaire data from almost 1400 women so far, only 438 of the baseline questionnaires have been key entered into a usable database. Table 1A and Table 1B show some characteristics of the study group based on these limited data. The mean age of the active duty women is 25 years compared to 26.5 years for military dependents. About 45% of the active duty women and 30% of the military dependents report that their highest education achieved is graduation from high school (Chart 1); less than half of each group attended college. Seventy nine percent of active duty women and 98% of the military dependents are married (Chart 2). The current median monthly income is low for both groups: $2225 for active duty mothers and $2458 for military dependents (Chart 3). The current sample is 57% white, 14% African American, 12% Hispanic, 7% Asian and the remaining women describe their race as "other" (Chart 4).

Table 2 is again based on the same small amount of data (from clinic questionnaires and/or medical record abstraction). Twenty three percent of the women report that they currently smoke cigarettes. The mean self-reported weight before pregnancy is 64.5 kg (SD=13.5 kg) and the mean pre-pregnancy body mass index (weight kg/height in cm^2) is 24.5 (SD=5.1). This BMI is somewhat higher than the mean BMI of 22 that is usually reported in the literature. We suspect that it reflects random variation in the subset of questionnaires that have been entered and we expect the BMI of the study group to decrease when all data are available. Thus, all preliminary data we report here should not be interpreted, but simply viewed as a snap-shot of the kinds of findings we will be reporting when data collection is complete. Mean prenatal weight gain of 15.3 kg (SD=5.7) is consistent with reports in other populations.

We have key-entered over 2700 of the clinic questionnaires collected, and these are the basis of the preliminary data we report on weight change. Mean maternal weight over the entire postpartum year is 68.8 kg (SD=11.9). Figure 1 shows the change in mean maternal weight from 3-7 days to 12 months postpartum based on cross-sectional data. There is a steady decrease over time, with the greatest differences occurring between the first newborn and second newborn visits (due to fluid changes) and again between the 9 month visit and 12 month visit. Figure 2 shows the same relationship using Body Mass Index (which reflects maternal weight adjusted for height).

Figure 3 compares changes in mean body mass index over the postpartum year by infant feeding method. There is little difference between exclusive breast-feeders, mixed feeders and exclusive bottle feeders. This finding is similar to previous studies.

Figure 4 compares changes in mean body mass index over the postpartum year by self-reported physical activity based on a single question: "During the last 7 days, how many times did you participate in a sport or exercise?" We have much more detailed data on physical activity to analyze in the future. Based on the cross-sectional responses, it is difficult to see a trend over time in Body Mass Index. However, at the 12 month postpartum visit, women who reported that they exercised more than 3 times a week had a BMI of 24.4 (SD=3.6) compared to 24.8 (SD=4.7) for those who reported 1-3 times a week. Those who reported no sports or exercise in the last 7 days had the highest BMI of 25.3 (SD=5.0).

Figure 5 compares BMI by military status. It can be clearly seen that by 6 months postpartum, the active duty group has a lower mean BMI than the dependent mothers, and this difference persists and increases at 9 and 12 months. In fact, the active duty group achieves a mean BMI of about 25 (consistent with the cut-off required to meet physical readiness standards) by 6 months postpartum, while the dependent mothers do not achieve this mean level by 12 months. Again, we stress that this is a very small preliminary subsample and these results are subject to change. Future analyses will focus in particularly on the number and characteristics of active duty women who do not reduce their BMI to below 25.

Figure 6 shows the prevalence of dieting practices reported by the limited sample according to infant age. Twenty eight percent of the women reported that they did nothing intentional to lose weight after birth. An additional 6% said that they worried about their weight, but did nothing. The most common methods used to lose weight included eating less, increasing physical activity, cutting down on "junk" food, eating low fat foods and skipping meals. Eleven percent of the women reported specifically attempting to eat a low calorie diet. Five percent reported that they tried to control their weight by smoking cigarettes, 4% used liquid diets and 3% took diet pills. In this small subsample, only 0.5% of military dependent women and 2.5% of active duty women reported that they went to a weight reduction program sponsored by the military. In future analyses we will examine these behaviors in greater detail and attempt to understand their relationship with actual weight change in the mothers.

Table 1A

Maternal Sociodemographic Characteristics Preliminary Data: ABC Study

	ALL (n= 438)	
	n	%*
Maternal Education		
< High School	25	5.7
High School	145	33.1
Vocational/Trade School	30	6.8
College	210	47.9
Post Graduate	26	5.9
Total	436	99.4
Current Marital Status		
Single	15	4
Married	412	94
Divorced/Separated	10	2
Widowed	1	<1
Total	438	100
Current Monthly Income		
<$500	2	<1
$500-1000	22	5
1000-1500	74	17
1500-2000	98	22
2000-2500	91	21
2500-3000	56	13
3000-6250	79	18
>6250	12	3
Decline	5	1
Total	439	100
Race-Ethnicity		
White	169	56
Black	47	16
Hispanic	35	12
Asian	30	10
Other	19	6
Missing	3	<1
Total	303	100
Number of Other Children		
0	242	56
1	123	29
2	55	13
≥ 3	12	2
Total	432	100
Median Income	$2,357	n = 434
Mother's mean age	26	n = 1943

* Some values may not total to 100% due to rounding

The following 5 charts are graphical representations of this data.

Table 1B

Maternal Sociodemographic Characteristics Preliminary Data: ABC Study

	ACTIVE DUTY (n = 83)		DEPENDENTS (n= 349)	
	n	%*	n	%*
Maternal Education				
< High School	0	0	25	5.7
High School	38	44.7	107	30.3
Vocational/Trade School	2	2.4	28	7.9
College	41	48.2	169	47.9
Post Graduate	4	4.7	22	6.2
Total	85	100	351	98
Current Marital Status				
Single	12	14	3	<1
Married	66	79	346	98
Divorced/Separated	6	0.7	4	1
Widowed	1	1	0	0
Total	85	94.7	353	99
Current Monthly Income				
<$500	0	0	2	<1
$500-1000	6	1	17	5
1000-1500	12	2	64	18
1500-2000	16	19	82	23
2000-2500	18	21	73	21
2500-3000	12	14	44	12
3000-6250	21	5	58	16
>6250	3	3	9	3
Decline	0	0	5	1
Total	88	65	354	99
Race-Ethnicity				
White	34	51	135	45
Black	12	18	35	15
Hispanic	11	16	24	10
Asian	6	9	24	10
Other	4	6	15	6
Missing	0	0	3	1
Total	67	100	236	87
Number of Other Children				
0	52	63	190	54
1	22	27	101	29
2	8	10	47	13
≥ 3	1	<1	11	3
Total	83	100	349	99
Median income	$2,225	n = 88	$2,458	n = 349
Mother's mean age	25	n = 429	26.5	n = 1494

Chart 1

Maternal Education (%) in Preliminary Data: ABC Study (n=436)

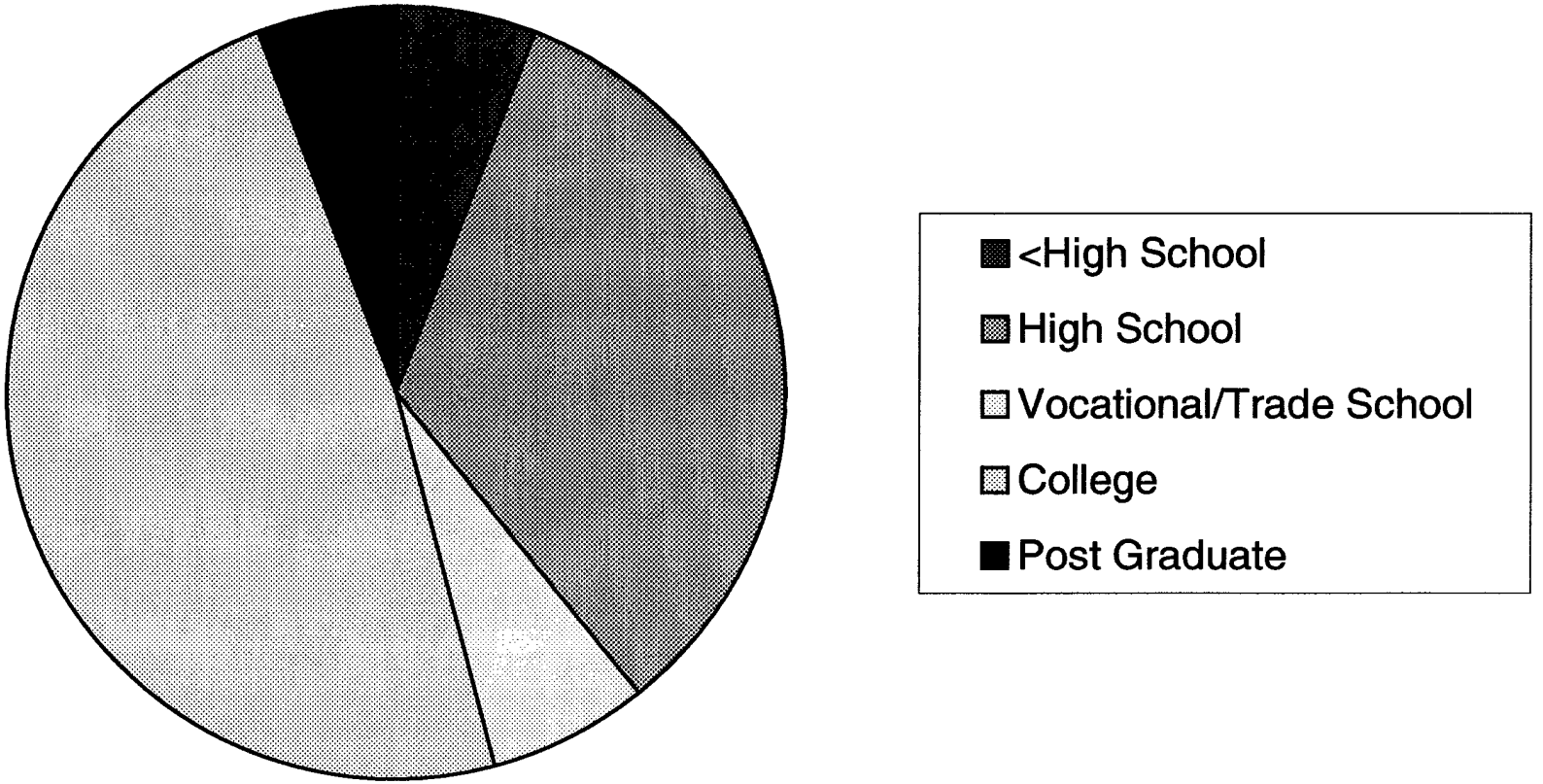


Chart 2

Current Marital Status (%) in Preliminary Data: ABC Study (n=438)

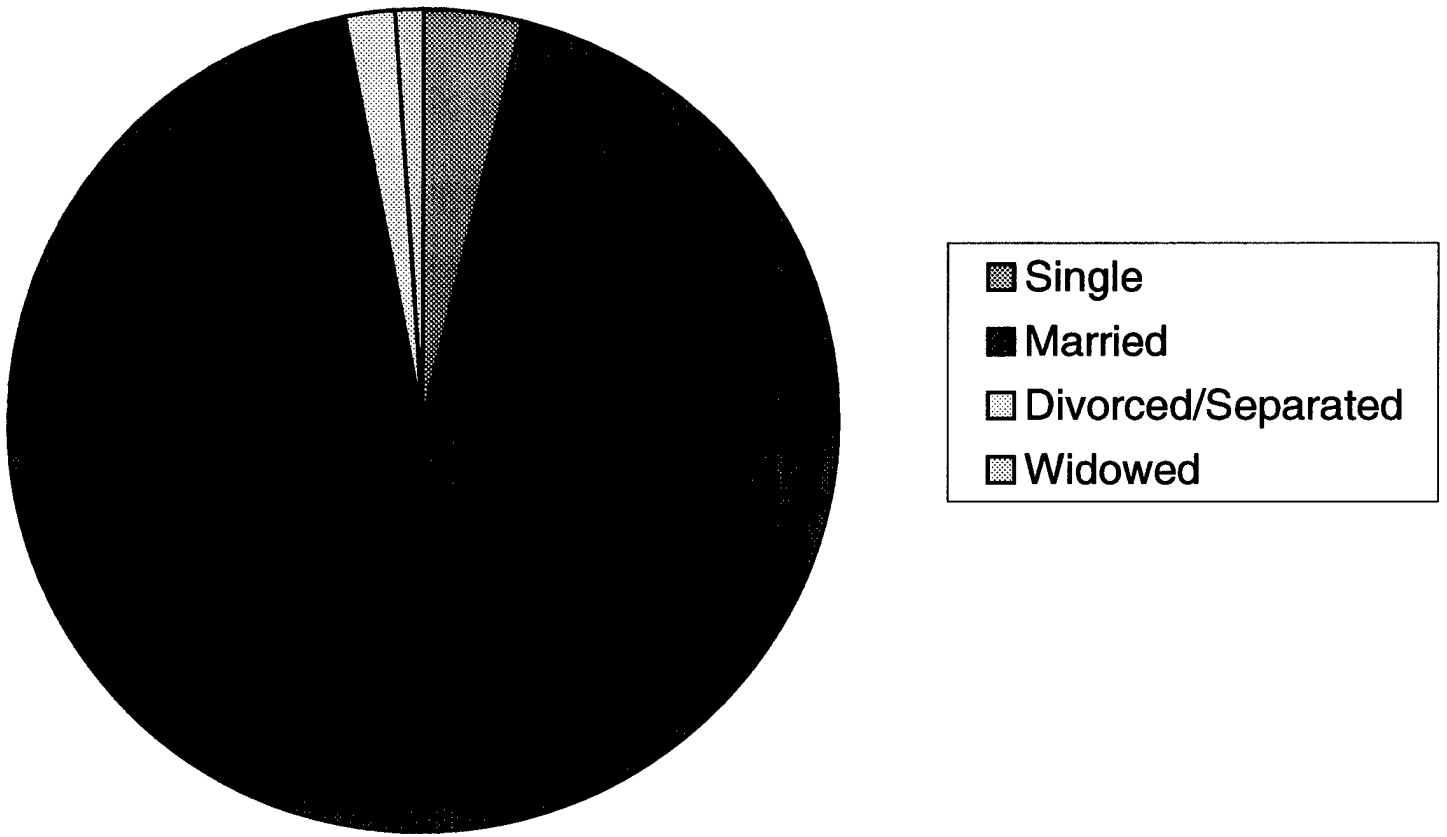
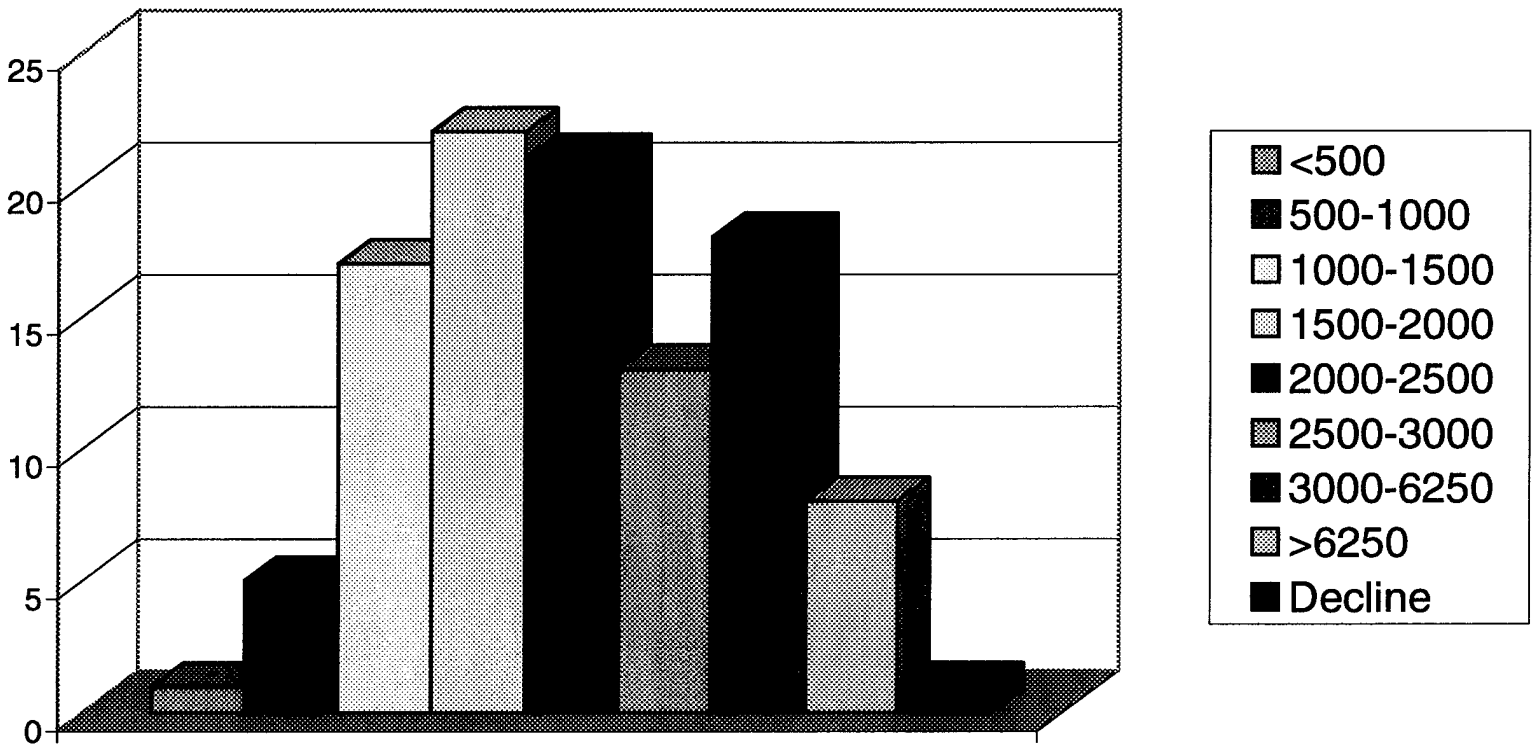


Chart 3

Current Monthly Income (%) in Preliminary Data: ABC Study (n=439)



Race-Ethnicity (%) in Preliminary Data: ABC Study (n=303)

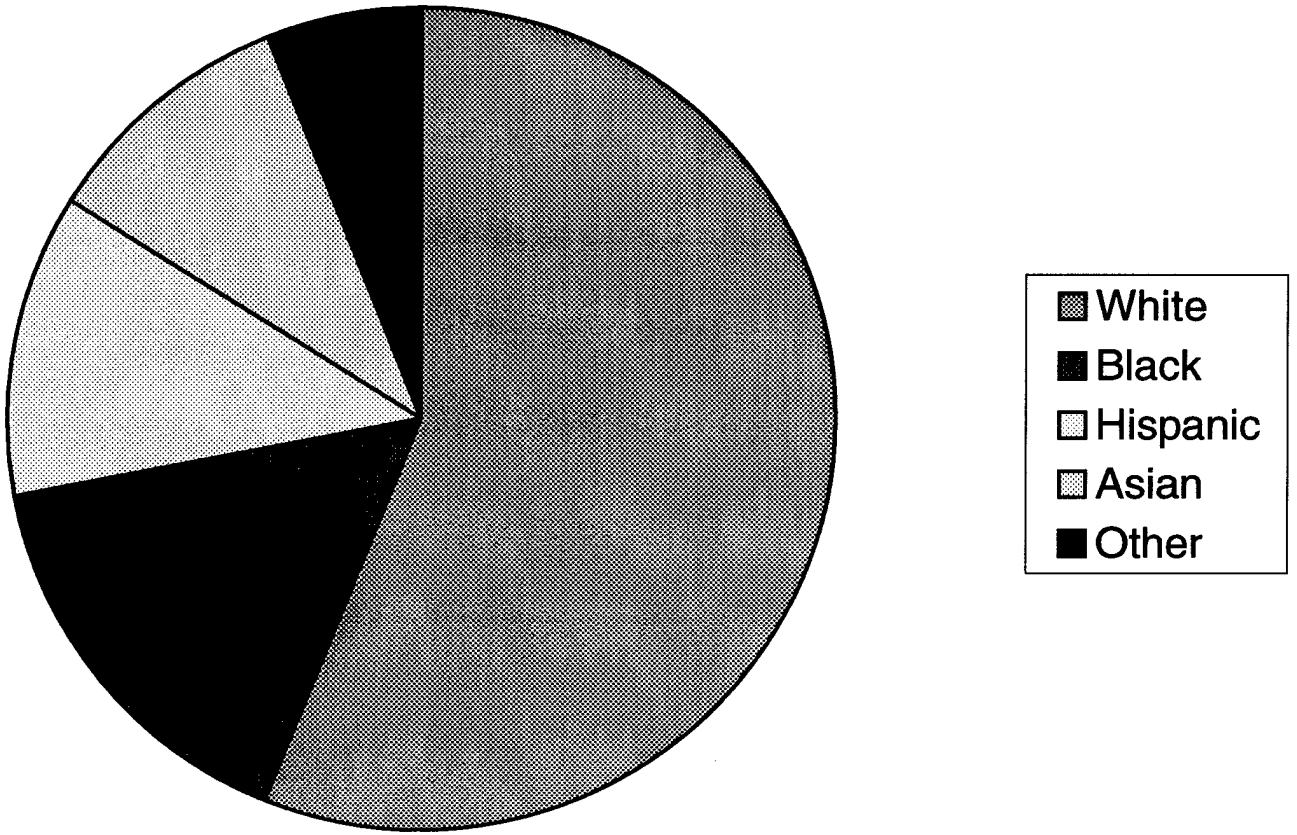


Chart 5

Number of Other Children (%) in Preliminary Data: ABC Study (n=432)

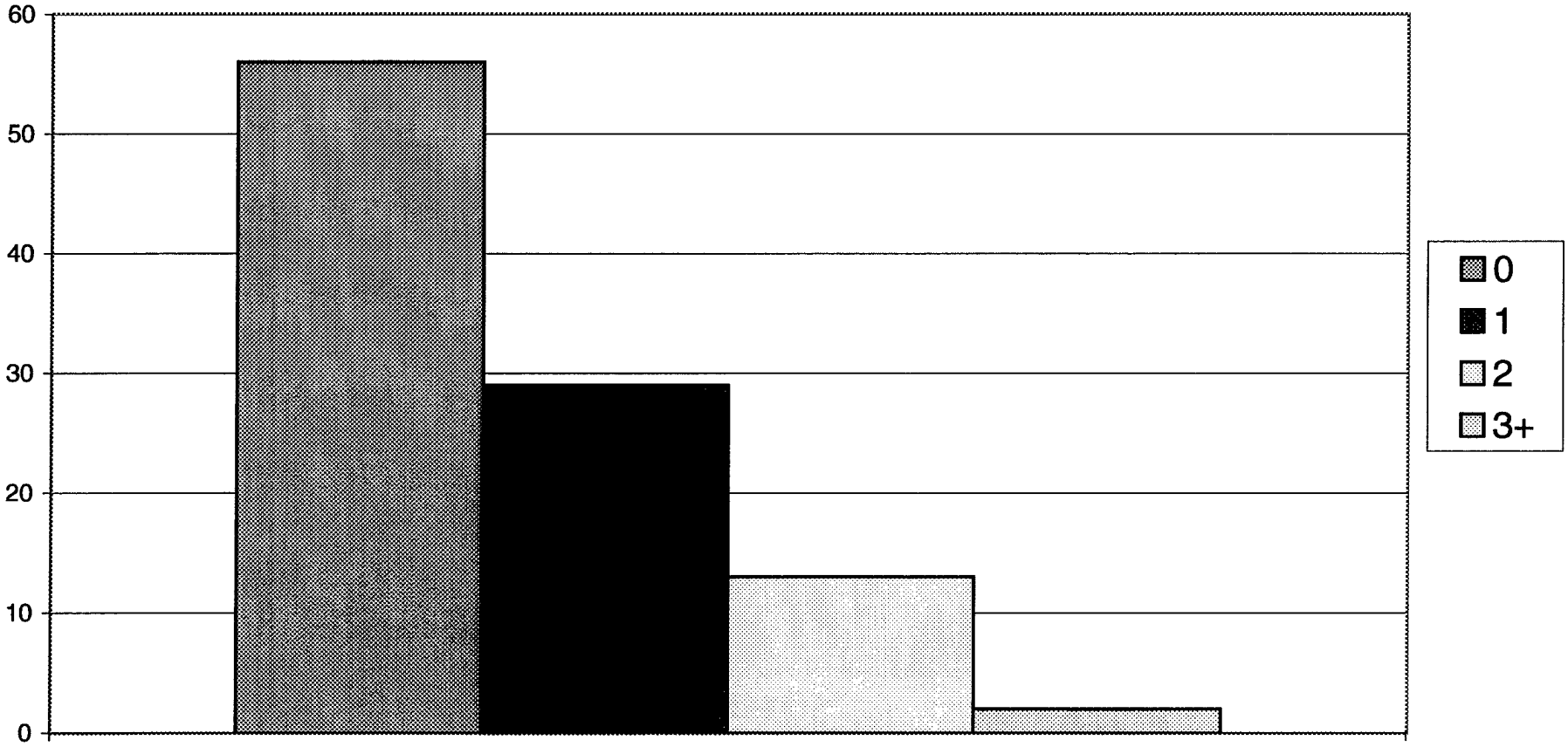


Table 2

Maternal Characteristics: Body Size and Smoking by Military Status
Preliminary Data: ABC Study

	ACTIVE DUTY			DEPENDENT			ALL		
	n	mean	SD	n	mean	SD	n	mean	SD
Height, cm	199	161.8	6.7	590	161.7	8.5	935	161.8	8
Pre-pregnancy BMI	67*	24.6	4.8	221*	24.6	5.3	728	24.5	5.1
Pre-pregnancy weight, kg	69*	63.8	11.8	231*	65.2	14.7	757	64.6	13.5
Weight gain in pregnancy, kg	102	15.1	5.5	372	15.5	5.7	531	15.3	5.7
Delivery weight, kg	103	80.2	14.7	375	81.8	16.2	479	81.5	15.9
% Current Cigarette Smokers	19	23%		55	16%		74	17%	

* Data on military status was not yet available for these variables for the majority of women

Figure 1

Change in Mean Maternal Weight Over Time - Preliminary Data: ABC Study

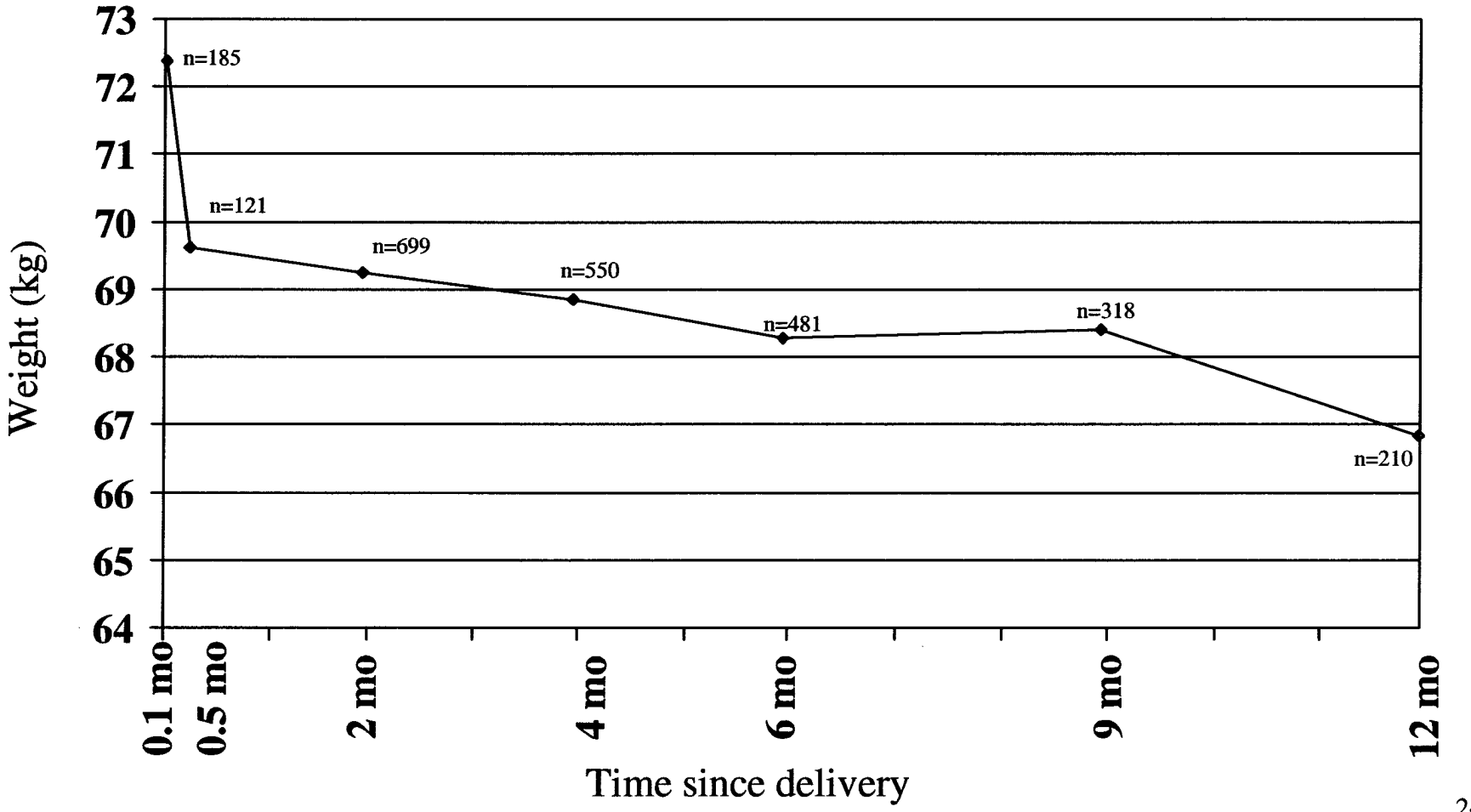
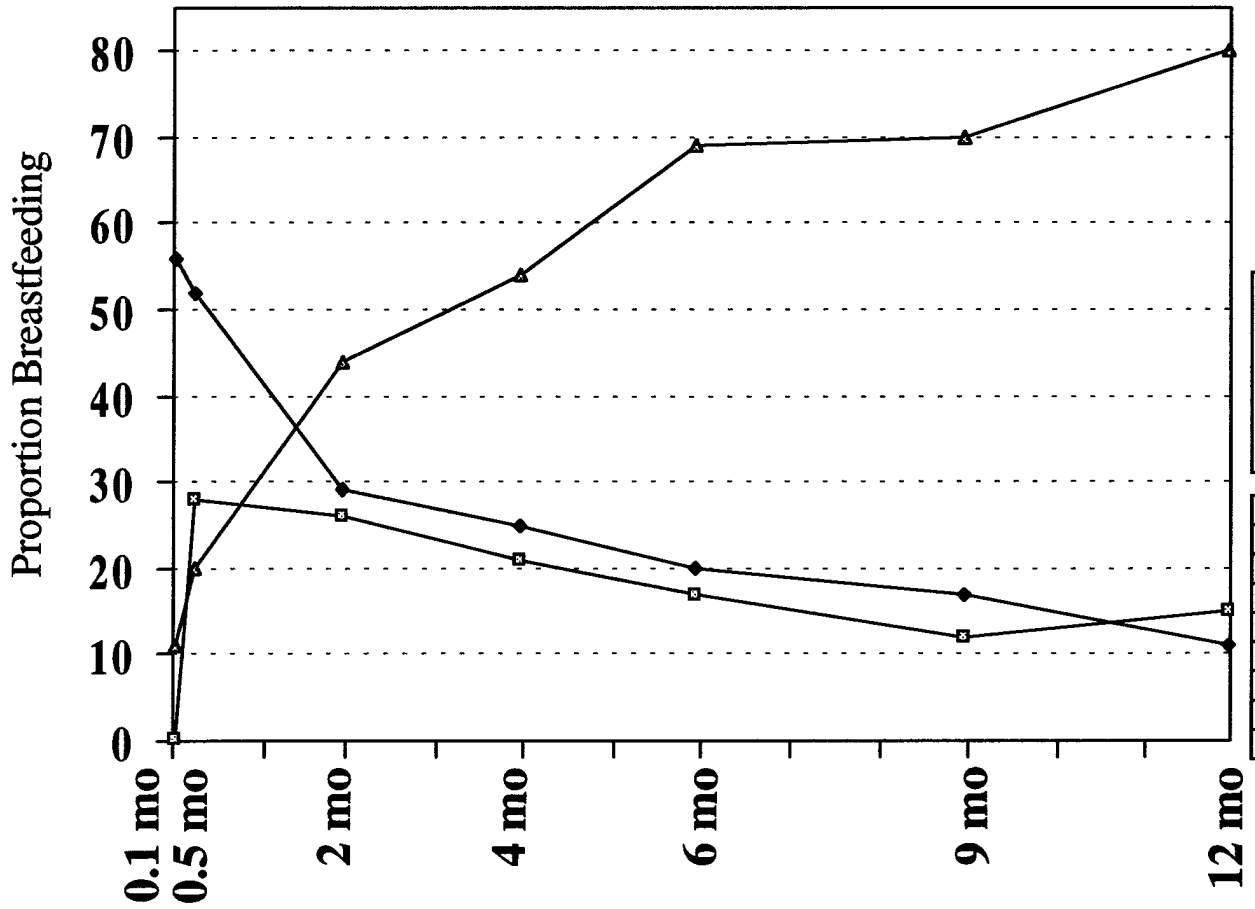


Figure 2

Overall Mean Postpartum BMI - Preliminary Data: ABC Study

Figure 3

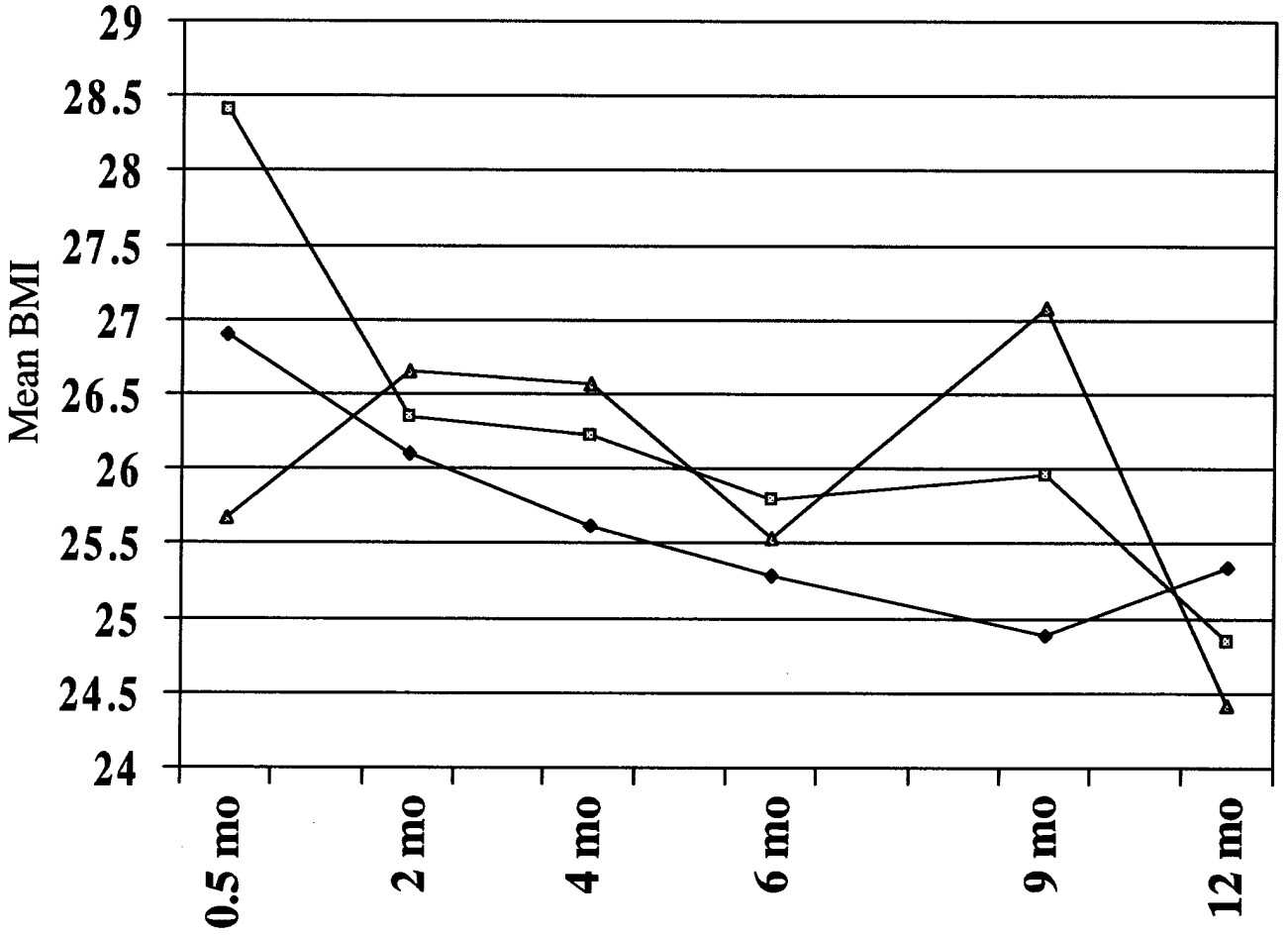
Change in Breastfeeding (%) - Preliminary Data: ABC Study



Number of Observations				
	Breastfeeding	Mixed	Bottle	Total
0.1 mo	105	62	20	187
0.5 mo	69	37	26	132
2 mo	211	187	318	716
4 mo	142	122	304	568
6 mo	98	85	333	516
9 mo	58	42	237	337
12 mo	11	34	177	222

Figure 4

Mean BMI by Postpartum Sports Participation - Preliminary Data: ABC Study



	Number of Observations		
	0	1-3	4+
0.5 mo	92	26	14
2 mo	297	244	170
4 mo	218	220	124
6 mo	191	199	118
9 mo	133	121	82
12 mo	93	87	47

Figure 5

Current BMI by Military Status - Preliminary Data: ABC Study

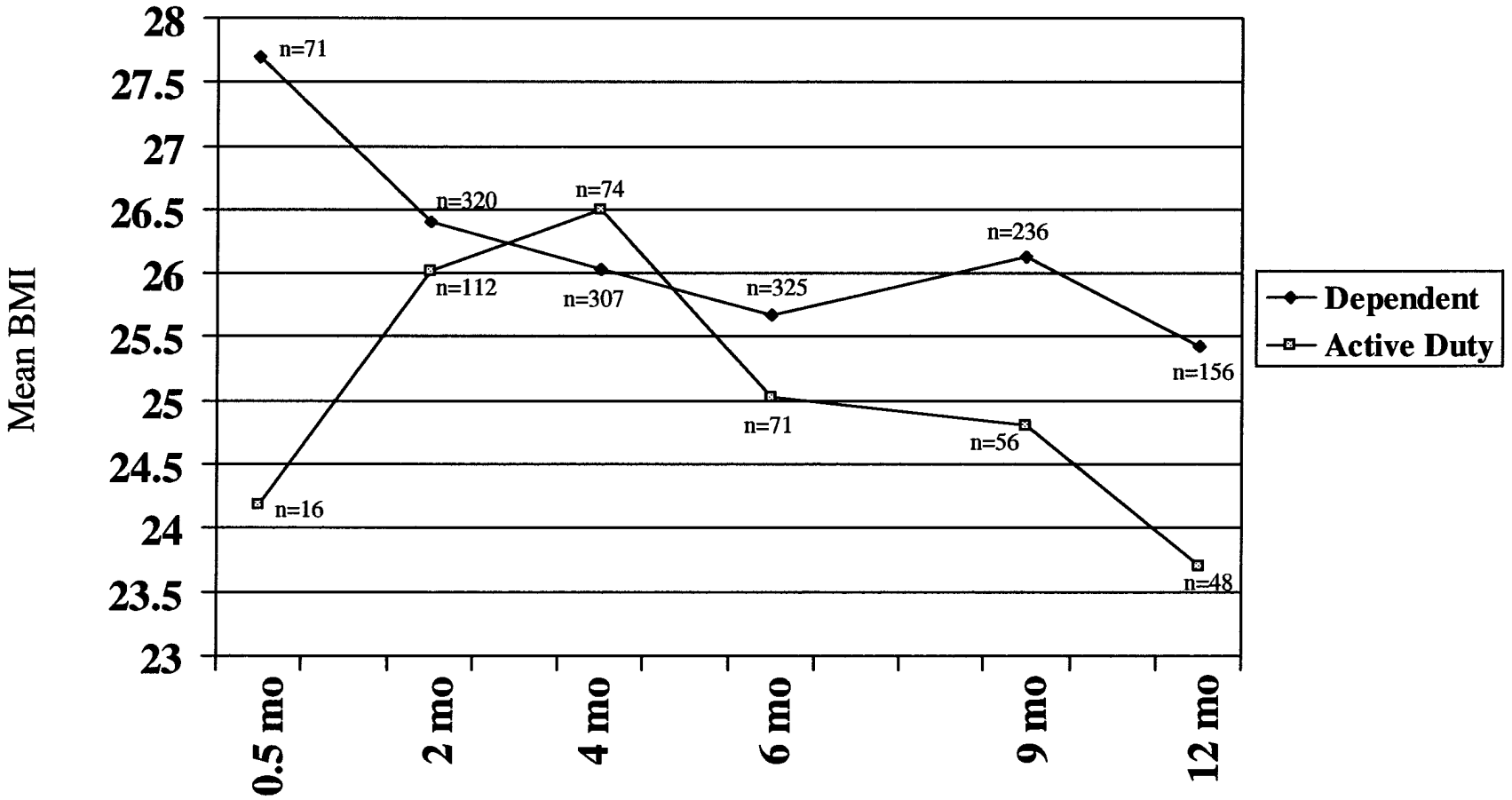
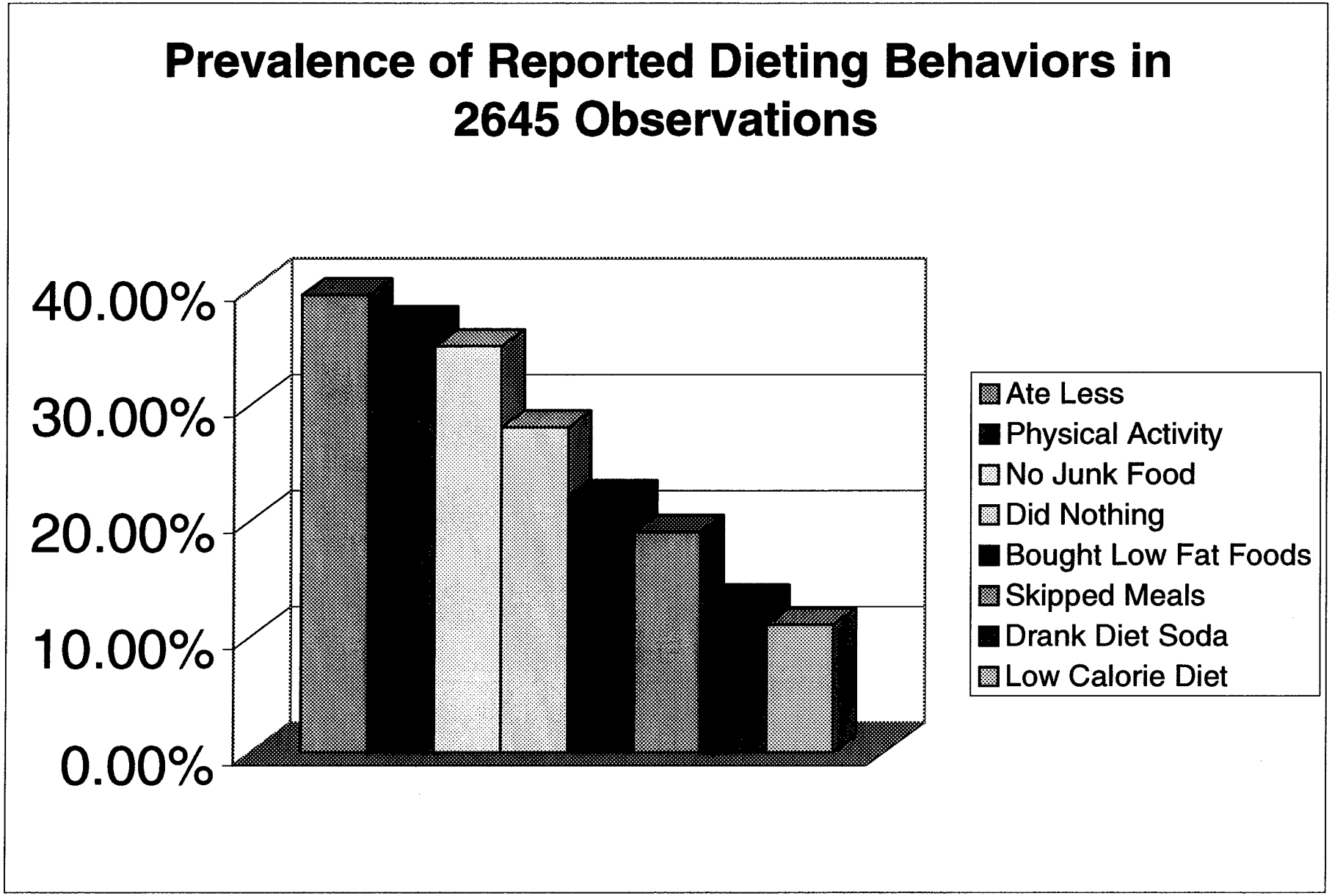


Figure 6


Prevalence of Reported Dieting Behaviors in 2645 Observations
40.00%
30.00%
20.00%
10.00%
0.00%
Ate Less
Physical Activity
No Junk Food
Did Nothing
Bought Low Fat Foods
Skipped Meals
Drank Diet Soda
Low Calorie Diet

Issues, Problems and Solutions

We have encountered a series of problems that are expected in clinic-based prospective studies. We believe that, given the complexity and multiple demands of the study, we have done a good job of addressing these problems, which we describe below. We continue to work toward procedures that will enhance follow-up for the duration of the study.

Switch from passive to active recruitment

In our original proposal, we planned to hire one or two research nurse-recruiters who would rely heavily on the Pediatrics Clinic appointment clerks, medical staff and corpman to "passively recruit" and "passively follow" our study participants. This approach was based on a small pilot survey that we conducted when preparing our proposal and advice from our Co-Investigators working in the Pediatrics Clinic. It was their impression that the NMCSD population of new mothers is exceptionally compliant to research studies, and they believed the women would be particularly interested in a study about themselves. However, although the response of the NMCSD Pediatrics staff has been enthusiastic and cooperative, we quickly discovered that "passive" recruitment and follow-up was untenable and the study population especially difficult to include in rigorous research. These women are facing the stresses of adjusting to the massive changes that occur after birth and the demands of caring for an infant. Current data suggest that 38% of the women in the study population have only a high school education and 44% report a monthly family income of less than $2,000. The study population also appears to be highly mobile within San Diego. For example, when we attempt to reach these women at home for follow-up phone calls within a week of their last clinic visit, 30% of the telephone numbers have been disconnected or changed. Finally, we suspect that women in our study population, like most American women, do not enjoy being weighed. All these factors have contributed to the need for a more structured approach to data collection.

The task of data collection is also demanding due to institutional factors. We do not have the resources to staff the Pediatrics Clinic during all the hours it is open, thus we are unable to recruit women who come in during un-staffed hours. It is difficult to consistently match recruiter hours to the flow of clinic traffic, since accurate appointment lists are not available until the day before. Last-minute changes in appointments or a flu epidemic often leave our research staff with few women to recruit on one day and far to many to handle on the next. (We have back up duties for the recruiters when this occurs so we can effectively use their time when not recruiting). Furthermore, within a given day, infant well-baby visits tend to clump together, and it is not unusual for a large group of well babies to arrive within 15 minutes. We have accommodated this trend by scheduling multiple recruiters to work during the times when the most well baby visits are usually scheduled. However, given the time required to complete an enrollment, even 3 recruiters cannot approach and enroll all the mothers who may appear and leave in a short time frame. Because the study is essentially a "guest" in the Pediatric Clinic, our staff must respect that delivering medical care of the babies is the highest priority. Thus, mothers are frequently called in to see the physician before the recruiter has completely introduced the study or even when the mother is in the middle of signing enrollment papers. Due to constraints in the Participant Tracking System, if the mother leaves before the recruiter can complete the screening process, that mother is considered "not approached". If a mother does not complete all the

paperwork and measurements before she leaves, she is not registered as a participant in the tracking system.

The length of the study Consent Form is also a major barrier to efficient and effective recruitment. To reduce participant burden, our original consent document (included in the research proposal and approved by the UC Berkeley Committee for Protection of Human Subjects) was only two pages in length and could be read and signed within several minutes. We considered this short Consent Form appropriate given that this is an observational study that collects only questionnaire and weight data and therefore confers no risk to human subjects. However, the process of seeking approval from the two other Human Use Committees who oversee the study yielded a much longer and more complex document. Our final approved study Consent Form is 7 pages long and requires 5 participant initials and dates, 5 witness initials and dates in addition to 2 full signatures by each participant and the witness. Our requests to shorten or change the format of this Consent Form were denied, so we adjusted our recruitment process to accommodate it. As all of our participants are caring for infants and literally have their arms full, the complicated process of reading and signing each Consent Form requires the full attention of a study staff member. With a shorter consent form, we could recruit a mother in 5-10 minutes, but with our current Consent Form, an experienced recruiter requires 15-20 minutes for to enroll a mother. A copy of the Consent Form in included in Appendix E.

To address these problems, we hired additional recruiters who approach as many women as possible to perform screening and enrollment and to support follow-up activities. The usual staffing pattern is 7 recruiters who work Monday through Friday in three shifts: 7:30 to 12:30; 8am to 1pm and 11am to 4pm. On Saturday, we cover the clinic from 7:30 am to 12:30 am, contingent on scheduled well baby visits. Actual clinic hours are much longer than this, as there are regularly scheduled evening and weekend well-baby visits that cannot be efficiently covered by the resources of the project. Although we attempt to reach our potential and enrolled participants through a passive process during unstaffed hours, effective data collection only occurs during visits during staffed hours.

In summary, the characteristics of the study population and the conditions of the clinic required that we adopt a far more labor-intensive recruitment procedure than we had anticipated. Given the resources of this project, it is not feasible or cost effective to hire enough staff to individually approach and recruit every eligible woman. For these reasons, we will fall short of our original intention to enroll 4000 women by the end of the study. However, we will enroll close to 3000 women and this sample will be sufficient to address the scientific goals of the study. Our ability to compare those in the study with those who did not participate will enhance the generalizability of our findings.

Change in Follow-up Procedures in the Clinic

Each well-baby visit also serves as an ABC Study visit. Ideally, each ABC mom identifies herself to the check-in clerk to initiate the follow-up study procedures. However, the ABC typical mother does not to identify herself as an ABC participant, despite posters asking her to do this, and the clerks are too busy to remember to ask this question consistently. We solved

this problem by putting a highly visible neon ABC sticker on each enrolled mother's infant chart (or encounter form if the chart is not available) so that the clerk can check for ABC status at every check-in and provide the mother with the study questionnaire. Additional training and on-going support for the clerks has increased the efficiency of this approach, which is now working well. Because an ABC participant will only appear on our Master appointment list if her appointment was pre-scheduled, and 20% of appointments are not, the sticker on her chart helps to alert the clerk to initiate the follow-up process even when we do not expect the mother to appear.

Even after receiving their questionnaire, some ABC participants forget to identify themselves to the corpsmen responsible for measuring weight. Despite large reminder posters next to the baby scales and in the exam rooms: "Are you an ABC mom? Don't forget to be weighed!," we have missed weight measurements. We have addressed this problem by placing an "ABC sticker" directly on each mother at check in, and by putting an additional "ABC sticker" on the clinical flow-sheet where infant weight is recorded by the corpsmen in the medical record. The corpsmen are trained to look for stickers in either location and then weigh the mother.

Our challenges did not end with the mothers. We discovered that some corpsmen resisted or neglected the extra work of weighing the mothers. When this problem became apparent, ABC staff took over the weighing of some moms until the problem could be resolved. Our close work with their supervisor solved the problem, and the corpsmen resumed their roles as the primary people to weigh the mothers. The most effective intervention for this problem was the offering of incentives to Corpsmen: each month, the corpsman that weighs the most ABC mothers receives special liberties and 2 movie passes. These changes have been highly effective. We have also recently implemented the process of recording the mother's weight both in the infant chart and on the clinic questionnaire. This ensures the collection of our primary outcome variable in situations where questionnaires are never returned.

We have also shifted more study staff time from recruitment to follow-up, with the objective of making at least a brief contact with every single returning ABC mom, and hopefully to collect each completed questionnaire. This approach is especially important for the 20% of mothers who do not appear on the Master list and therefore are most likely to fall through the cracks. Given the resources of this project, this "active follow-up" cannot be provided for every woman, but it is the most effective approach and we are doing our best to provide it.

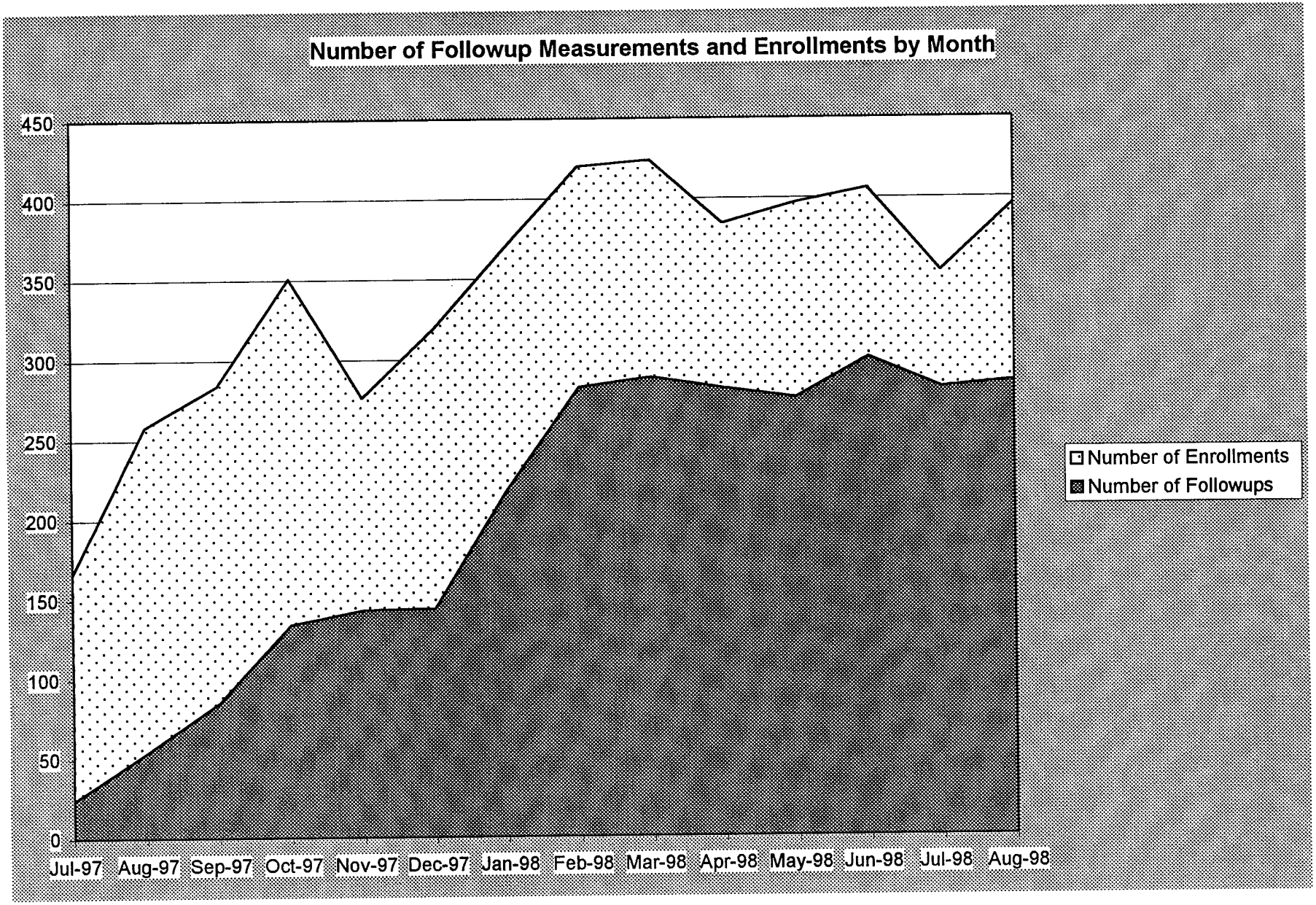
Figure 7 shows that these modified protocols for follow-up (put into place in late Fall, 1997) have yielded a dramatic increase in the collection of follow-up data.

The NMCSD Pediatrics Clinic opened a satellite clinic this year at North Island. Some of our already-enrolled mothers switched to that facility. We were able to implement study procedures there and have been able to retain these mothers in the study from that remote location.

Tracking of Follow-up Measurements

Our ability to effectively track follow-ups in individual mothers has been limited by the large number of "walk-in" and other appointments that don't originally appear in the CHCS. Because the CHCS download for a given day is not reliable, the Navy updates it after the fact to correct for "same day" appointments, cancellations, no-shows, well-baby appointments that were booked into "acute" slots and "acute" appointments that were booked into well-baby slots. It

Figure 7


Number of Followup Measurements and Enrollments by Month
450
400
350
300
250
200
150
100
50
0
Jul-97
Aug-97
Sep-97
Oct-97
Nov-97
Dec-97
Jan-98
Feb-98
Mar-98
Apr-98
May-98
Jun-98
Jul-98
Aug-98
Number of Enrollments
Number of Followups

required almost two years of collaboration between with the Navy and our study programmer to allow us to use the "post-appointment adjusted" CHCS to reconcile our Participant Tracking System. A comparison of our computerized data and well baby charts for several randomly selected days indicated that there is almost 95% agreement between the visits that actually occurred and those that appear in our "post-adjusted" Participant Tracking System during the same period. This confirms that the system accurately describes the well-baby appointments that occur.

Because the final problems with the post-appointment adjusted Participant Tracking System have only recently been resolved, we are not yet able to provide reliable data on individual follow-ups for the study in this report. We have begun the complex computer programming required to quantify in detail the follow-up data for each woman that contribute to the cohort portion of the study. However, we provide data on the total number of follow-up measures obtained in relation to the number of well-baby visits for study women.

Addition of a follow-up telephone protocol

Follow-up questionnaires and weight measurements can be lost if a mother is not identified and leaves without providing the information, if she completes the information but forgets to turn in her questionnaire or if she sends the infant for their well-baby visit with the father or another relative. If a clinic questionnaire is missing for a well-baby visit on the appointment list, study staff check the infant's medical record for a maternal weight measurement. If this is not available, we call mothers who we missed in the clinic to ask for a self-reported weight for that day. (We ask the mother to weigh herself on a scale if available. When these data are entered, they are flagged as "self-reported" weights for later analyses.) These telephone calls requesting self-reported weight began this summer. The procedures have been further refined during the month of October to include 5 important questions from the clinic questionnaire as well. However, our study population is so mobile, that half of the calls we make within a week of the last well-baby visits yield disconnected phone numbers. Furthermore, we are unable to reach another group of women with working phone numbers after 3-5 repeat calls. We trace the women as well as we can, and ultimately we obtain the follow-up data for about 50% of the missed follow-up visits. Details on our phone protocol are available in Appendix F.

Improving Response to Take Home Questionnaires:

Originally we handed out the Baseline questionnaire in the enrollment packet with a self-addressed, stamped envelope. When completed, it was mailed to San Francisco and the participant received $10 in the return mail to compensate her for her time. However, response to this approach was poor, and we changed to distributing all take home questionnaires through regular mailings, triggered by the baby's birth date. Repeated mailings improved the initial response rate somewhat, but overall the response was disappointing. For example, by May we had enrolled 1800 women, but only 850 Baseline questionnaires had been returned. While this is not surprising given the length of the questionnaire and the busy lives of our participants, we did not want to abandon the detailed data measured by the take home instruments.

In June we undertook a telephone survey to attempt to assess why the response to the take home questionnaires was unsatisfactory. We called a stratified (on infant age), random sample

of women who had failed to return one or more take home questionnaires. Of the 77 women called, 32 (42%) had disconnected phone numbers and could never be reached. Six (8%) said they had never receive the questionnaire, 21 (27%) were unreachable after at least two attempts and 21 (27%) had received a questionnaire. These last 21 women had few suggestions about improving the response rate and could not pin point why they had not returned their take-home questionnaires. We immediately re-mailed the questionnaires to the women we reached, including those who had never received one. By the end of August, only 1/3 of these women had returned the take-home questionnaire.

Despite the fact that our telephone survey yielded no obvious solutions for improving response rates, we implemented major changes to try and improve them. We removed the food frequency questionnaire from the Follow-up questionnaire to shorten it. We resumed the process of personally giving each mother her take-home questionnaire in the clinic, in addition to continuing our mailed protocol. We added a "take-home questionnaire" code to the master recruitment list to inform recruiters the appropriate take-home questionnaire to provide to participants. Recruiters were also trained to emphasize how important the questionnaire information is to the success of the study. We revised the mailing protocol and created more aggressive procedures for investigating and correcting outdated addresses, re-mailing questionnaires to the new addresses or to the home-of-record. We now utilize several procedures for maintaining updated addresses in our database including asking for address and phone number updates on the cover of each clinic questionnaire. We switched from monthly mailings to every other month in order to limit the number of duplicate questionnaires received by the study participants. We switched from monthly mailings of incentive checks to bi-monthly mailings. In addition, we included a baby food cookbook as an up-front incentive to help mothers feel invested in the study and hopefully motivate them to return the take-home questionnaires.

These changes are successful. In August, we saw an increase in returns of 115% for the Follow-up questionnaire, 61% for 12 Month Enrollment questionnaire and 25% for the Baseline questionnaire.

Assessment of Selection Bias

Our Participant Tracking System indicates that, as of September 1, 1998, there were 985 women with infants of eligible ages who have not yet been approached by our recruiters. To improve recruitment of these women, we propose the following steps during the next few months:

- We plan to personally contact these women by mail and invite them to join the study. This approach will be implemented as soon as we can apply for permission to modify our Human Subjects protocol.
- We plan to stop enrolling newborn infants (who will only achieve an age of 4 months by the end of data collection) and shift all attention to older infants with the greatest emphasis on the 6, 9 and 12 month infants. This will also ensure that we encounter as many follow-ups in the older age groups as possible.
- To assess the possibility of selection bias in our non-approached mothers, we plan to conduct a mailed survey to a random sample of these women. The one-page questionnaire will assess whether the mother would have been eligible for the study and it

will also ask about additional characteristics of the mother, including her pre-pregnancy weight, her current weight, and her level of concern about postpartum weight loss. This procedure will begin as soon as we can apply for permission to modify our Human Subjects protocol.

Use of additional incentives

Although we have linked participation with well-baby visits and attempted to limit the participant burden of the data collection process as much as possible, participating in the ABC study takes a mother's time and energy. We have created a variety of outreach materials, which in addition to generating interest in the project among potential recruits, also serve as a point of reconnection with mothers that are already in the study helping to increase our follow-up success. This includes a brief child development newsletter corresponding with each well baby visit which is available to all women using the Pediatrics Clinic and which includes information on how to join the study.

We believe that one way to increase the effectiveness of recruitment and follow-up would be to offer a specific incentive for each measurement we collect. We already reimburse each mother $10 per take home questionnaire by mail, but this seems insubstantial given the amount of data we seek from our participants. This past September, we began to distribute a "Land Before Time Beanie Dinosaur" to all ABC participants and to each non-participant who was willing to be screened for the study. These toys were donated to the study by Equity Toys in San Francisco, and their appearance in the clinic created a great deal of enthusiasm and corresponds with an increase in enrollments during that month. We would like to be able to obtain additional donations or funds to purchase small incentive gifts for the future, though this does not seem possible at this point. We therefore are depending on regular mailings to enrolled moms to support follow-up activities. A mailed newsletter or card can serve as a reminder of the study to participants and validation of their importance to the research. Because there is a time gap between appointments, we hope that mailings also help to maintain continuity.

Progress in Terms of Technical Objectives

- Task 1: Hold advisory meeting. Finalize protocol, hire staff, field-test data collection methods. Begin recruiting women. Except for the advisory meeting, these tasks are complete. We have chosen to delay a formal meeting with our Advisory Committee until we have sufficient data to share with them. However, we have contacted some members of the Advisory Committee for expert input and responses to our questionnaires/data collection procedures on an individual basis and will continue to do this.

- Task 2: (proposed months 4-28)
  a. Collect data on 4000 women during the first year after birth. Recruit subjects, collect postpartum maternal weight measurements and questionnaires. Edit, code and enter data.

These activities are well underway. Field data collection is going well. This time last year we had enrolled a total of 622 postpartum women into our study and we had collected follow-up data of 800 questionnaires. As of September 30, 1998 we have enrolled 2264 women. We have collected 5624 clinic questionnaires and almost 2000 take-home questionnaires. After a slow start, data entry activities are now successfully underway.
b. Obtain/abstract prenatal medical records, enter data. Progressing well.
c. Create a preliminary analytical data set by merging these data sources. Clean/edit data. Using this preliminary data set, begin programming data analyses for tasks 3-6. Creation of the preliminary data set is accomplished. Preliminary analyses are reported.

- Task 3: Use parametric techniques to summarize the sequential measurements to provide estimates of the overall pattern of maternal weight gain during pregnancy and the pattern of maternal weight loss after birth. (proposed months 18-29). This task requires longitudinal data on prenatal weight and postpartum weight loss. As soon as sufficient data are available for analysis, we will begin this work which will be directed by Steve Selvin, the project statistician. He will apply statistical methods to all measured weights from the maternal obstetrical records to summarize the pattern of prenatal weight gain and to all measured well-baby clinic weights to summarize postpartum weight loss. We will commence this refinement of these variables on the subset of data that are entered and available, and apply the results to the entire study group when all data are available.

- Task 4: Describe the postpartum weight loss pattern and prevalence of excesive weight retention at 2 weeks, 2,4,6,9 and 12 months after delivery, by military status, racea dn other maternal characteristics, comparing results using several definition of postpartum weight retention. (proposed months 18-29) This process has begun and preliminary results are reported in this report.

The following Tasks will be addressed during the coming year:

Tasks 5-9 (proposed months 26-46): Use multivariate statistical methods to

- test the hypothesis that a high maternal weight gain during pregnancy, especially during the first and third trimesters, will be associated with excessive maternal weight retention, after adjusting for potentially confounding variables including military status, and risk factors.
- Using bivariate and multivariate statistical models, examine how maternal circumstances (e.g. education, socioeconomic status, marital status, work, social support), and lifestyle behaviors during the postpartum period (including method of infant feeding, reported physical activity, dieting behavior, attitudes toward body size, work hours, sleep) relate to maternal change and excessive weight retention.

- Use the results of previous analyses to attempt to identify those women who are most likely to become overweight as a result of childbearing, and to identify when postpartum (or during pregnancy) such women might be detected.

REFERENCES

1. Ohlin, A. and S. Rossner. Maternal body weight development after pregnancy. Int J Obesity, 1990. 14: 159-73.
2. Schauberger, C., B. Rooney, and L. Brimer. Factors that influence weight loss in the puerperium. Obstet Gynecol, 1992. 79: 424-429.
3. Abrams, B. and C. Berman. Women, nutrition and health. Curr Probl Obstet Gynecol Fertil, 1993. 16:3-61.
4. Institute of Medicine, Body Composition and Physical Performance. 1992, Washington, DC: National Academy Press.
5. Institute of Medicine, Nutrition during Pregnancy, Weight Gain and Nutrient Supplements. Report of the Subcommittee on Nutritional Status and Weight Gain during Pregnancy, Subcommittee on Dietary Intake and Nutrient Supplements during Pregnancy, Committee on Nutritional Status during Pregnancy and Lactation, Food and Nutrition Board. 1990, Washington, DC: National Academy Press. 1-233.
6. Keppel, K. and S. Taffel. Pregnancy-related weight gain and retention: implications of the 1990 Institute of Medicine Guidelines. Am J Public Health, 1993. 83: 1100-3.
7. Parnham, E., M. Astrom, and S. King. The association of pregnancy weight gain with mother's postpartum weight. J am Diet Assoc, 1990. 90:550-4.
8. Potter, S., et al. Does infant feeding method influence maternal postpartum weight loss? J Am Diet Assoc, 1991. 91: 441-6.
9. Smith, D., et al. Longitudinal change in adiposity associated with pregnancy. JAMA, 1994. 271: 1747-1751.
10. Lederman, S. The effect of pregnancy weight gain on later obesity. Obstet Gynecol, 1993. 79:424-9.
11. Parker, J. and B. Abrams. Differences in postpartum weight retention between black and white mothers. Obstet Gynecol, 1993. 81:768-774.
12. Scholl TO; Hediger ML; Schall JI; Ances IG; Smith WK.Gestational weight gain, pregnancy outcome, and postpartum weight retention. Obstet Gynecol,1995. 86:423-427.
13. Boardley DJ; Sargent RG; Coker AL; Hussey JR; Sharpe PA.The relationship between diet, activity, and other factors, and postpartum weight change by race.Obstetrics and Gynecology, 1995 Nov, 86(5):834-8.
14. Dewey, K. and M. McCrory. Effects of dieting and physical activity on pregnancy and lactation. Am J Clin Nutr, 1994. 1994:46S-53S.
15. Ohlin, A. and S. Rossner. Trends in eating patterns, physical activity and sociodemographic factors in relation to postpartum body weight development. Br J Nutr, 1994. 41:457-470.
16. Institute of Medicine, Nutrition during Lactation. Report of the Subcommittee on Nutrition during Lactation, Committee on Nutritional Status during Pregnancy and Lactation, Food and Nutrition Board. 1991, Washington, DC: National Academy Press.
17. Brewer, M., M. Bates, and L. Vannoy. Postpartum weight changes in maternal weight and body fat depots in lactating vs nonlactating women. Am J Clin Nutr, 1989. 49:259-65.
18. Dewey, K., M. Heinig, and L. Nommsen. Maternal weight-loss patterns during prolonged lactation. Am J Clin Nutr, 1993. 58:162-6.

19. Rossner, S. Pregnancy, weight cycling and weight gain in obesity. Int J Obesity, 1991.16: 145-147.
20. Parker, J. Weight Change Postpartum. Clinical Obstetrics and Gynecology, 1994. 37:528-537.
21. Abrams B. Prenatal weight gain and postpartum retention: a delicate balance. Am J Public Health, 1993. 83:1082-1084.
22. Abrams, B., and S. Selvin. Maternal weight gain pattern and birth weight. Obstet Gynecol, 1995. 86:163-169.
23. Luke B; Hediger ML; Scholl TO.Point of diminishing returns: when does gestational weight gain cease benefiting birthweight and begin adding to maternal obesity? J Maternal Fetal Med, 1996 5168-73.
24. Muscati SK; Gray-Donald K; Koski KG.Timing of weight gain during pregnancy: promoting fetal growth and minimizing maternal weight retention.Int J Obesity and Related Metabolic Disorders, 1996. 20:526-32.
25. Radloff LS. The CES-D Scale: a self-report depression scale for research in the general population. J Appl Psychol Meas 1977: 1 385-401.
26. Pop VJ, Komproe IH, van Son MJ. Characteristics of the Edinborough Postnatal Depression Scale in the Netherlands. J of Affective Disorders 1992. 26: 105-10.
27. Labbok MH, Krasovec K. Toward consistency in breastfeeding definitions. Stud Fam Plann 1990.21:226-230.
28. West CP. Factors influencing the duration of breast-feeding. J Biosoc Sci ,1980.12:325.
29. Stunkard AJ, Sorensen T, Schulsinger F. Use of the Danish Adoption Register for the Study of Obesity and Thinness. in: The Genetics of Neurological and Psychiatric Disorders (Edited by Kety S), pp 115-120. New York: Raven Press, 1983.
30. Davies K, Wardle J. Body Image and Dieting in Pregnancy.J of Psychosomatic Res. 1994,38:787-799.
31. Horm J, Anderson K.Who in America Is Trying To Lose Weight? Ann Intern Med. 1993, 119:672-676.
32. Serdula MK; Collins ME; Williamson DF; Anda RF; Pamuk E; Byers TE. Weight control practices of U.S. adolescents and adults. AnnInternal Med. 1993, 119:667-71
33. Paffenbarger, R., Jr, R. Hyde, and A. Wing. Physical activity, all-cause mortality and longevity of college alumni. N Engl J Med, 1986. 314: 605-613.
34. Lee, I., R.J. Paffenbarger, and C. Hsieh. Physical activity and risk of prostatic cancer among college alumni. Am J Epidemiol, 1992. 135: 169-179.
35. Helmrich, S., et al. Physical activity and reduced occurrence of non-insulin dependent diabetes mellitus. N Engl J Med, 1991. 325: 1101-1105.
36. Jacobs, D.J., et al. A simultaneous evaluation of 10 commonly used physical activity questionnaires. Med Sci Sports Exerc, 1993. 25: 81-91.
37. Ainsworth, B., et al. Conpendium of physical activities: classification of energy costs of human physical activities. Med Sci Sports Exerc, 1993. 25: 71-80.
38. Baecke, J., J. Burema, and J. Fritjers. A short questionnaire for the measurement of habitual physical activity in epidemiological studies. Am J Clin Nutr, 1982. 36: p. 936-942.
39. Block G, Hartman A, Dresser C et al. A data-gased approach to diet questionnaire design and testing. Am J Epidemiol 1986,124:453-469.

Appendix A: ABC Study Recruiter's Manual

Appendix B: Selected Questionnaires

2, 4, 6, 9 and 12 Month Clinic Questionnaire

Baseline Questionnaire

Appendix C: Medical Records Abstraction Form

Appendix D: Schematic of Data Management in San Francisco

Appendix E: Consent Form

Appendix F: Telephone Protocol and Interview

The ABC Study Background and Recruiter's Role

The ABC Study is being conducted by researchers from the Naval Departments of Pediatrics and Ob/Gyn in collaboration with the School of Public Health at the University of California at Berkeley (UCB) under a Department of Defense grant. Freeman, Sullivan & Co. has been subcontracted by UCB to collect the data in San Diego.

What is the study about?
The ABC Study will describe postpartum weight patterns and how maternal lifestyles, body weight, and fitness change in active-duty military women and military dependents through the first year of their baby's life. It will also retrospectively study how a mother's weight gain during pregnancy affects the size and health of her baby.

The information on mothers' health during the first postpartum year obtained by this study will provide a scientific basis for developing policies for active duty mothers, and may help shape realistic, scientifically grounded expectations of active duty mothers following their pregnancies.

Who can be in the study?
The ABC study is open to all active duty military women and dependents (wives of military men) with babies between the ages of 3 days-12 months who meet the eligibility criteria of the study (e.g., intend to bring baby into pediatric clinic at Balboa Naval Medical Center (NMCSD) or North Island (NI) for routine well-baby care beyond 2 mos. of age). Our goal is to collect information on over 4,000 pairs of mothers and babies.

When can a mother be enrolled?
Mothers can be enrolled at any point during the child's first year. While it is ideal to enroll a new mom immediately after birth and follow her through the entire first year, mothers can be recruited at any time during their child's first year and can participate for only one or two visits. However, women who bring their newborns to Balboa for a 3 day or 2 week check only, and plan to get their well-baby care somewhere besides Balboa or North Island should not be enrolled (as set out in the eligibility requirements of the screener).

What does the study involve for the mothers?
- Getting weighed and filling out a questionnaire at each well-baby appointment until the child is 1 yr old.
- Completing two longer take-home questionnaires:
  1) The "Baseline" Questionnaire: completed at the 2 mo. visit, or at enrollment when the child is older than 2 mos. and less than 12 mos.
  2) The "Follow-up" (Exit) Questionnaire: completed when the child is 12 mos. of age *if* the mom has completed a Baseline Questionnaire.
  3) Mothers who enroll when their child is 12 months will complete only one take-home questionnaire, the "12 -Mo. Moms" (Baseline-Exit) Questionnaire, a combination of the two take-home questionnaires the other mothers receive. This questionnaire is also given to mothers who enrolled prior to 12 mos. if their child turns 12 mos. and they haven't completed a Baseline Questionnaire.
- Moms will be paid ten dollars for completing each take-home questionnaire.

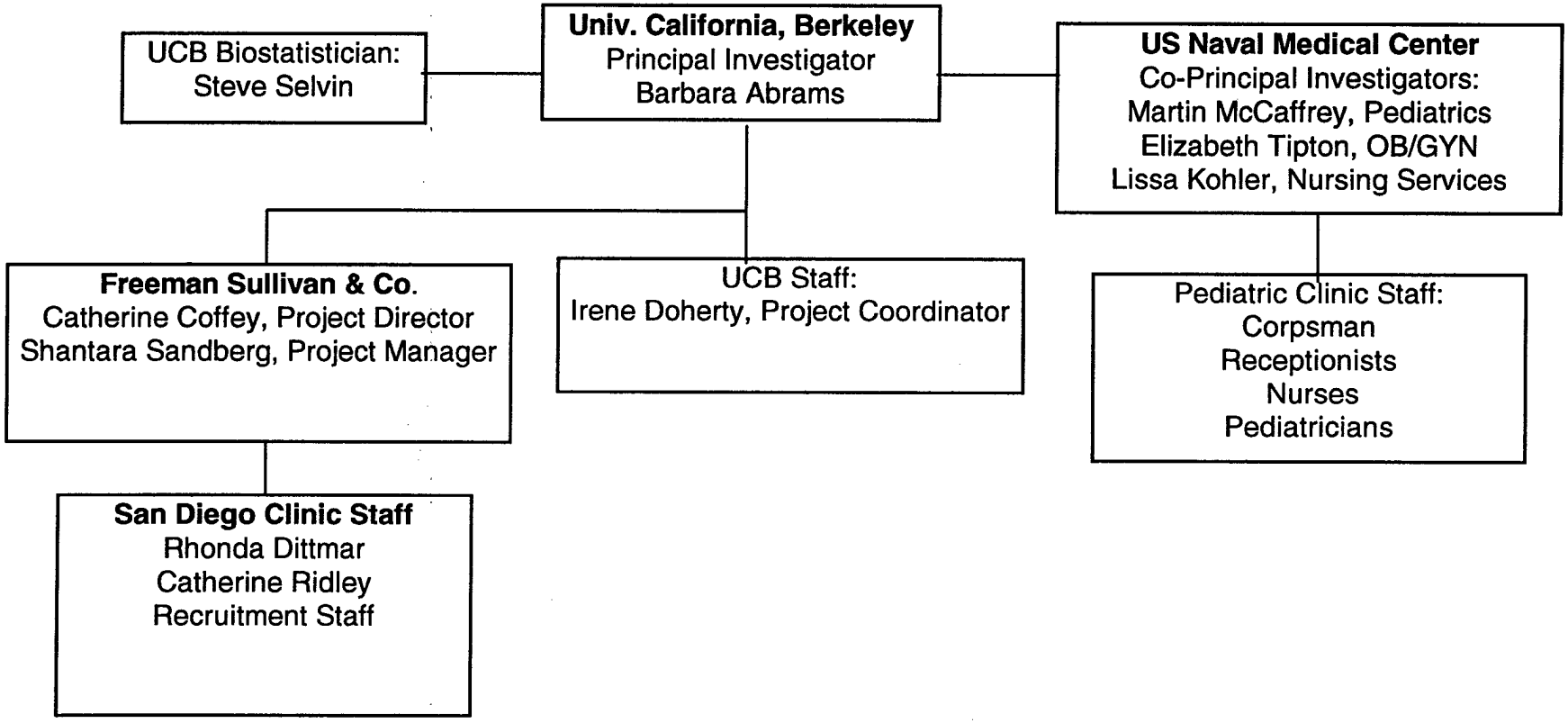
- ***These take-home questionnaires are really important.*** A mother is not considered a true ("qualified") ABC participant until she has completed (1) a Baseline or 12-Mo. Mom take-home questionnaire, and (2) at least one clinic questionnaire at a 2 mo. - 12 mo. visit.
- The study does *not* require any extra visits, invasive procedures or specimen collection.
- Pregnancy information will be abstracted from the participant's medical records.
- Active duty mothers' Physical Readiness Test results may be obtained from their personnel files.

What does a recruiter have to do?

A recruiter's duties include:

- Finding mothers to enroll into the study.
- Screening mothers to ensure that they are eligible to participate.
- Obtaining the written consent of eligible mothers agreeing to be in the study.
- Obtaining a medical records release form from eligible mothers agreeing to be in the study.
- Making sure participants fill out the appropriate self administered clinic questionnaires and that their height and weight are measured before they leave the clinic.
- Handing out the various take-home questionnaires as appropriate.

ABC Study
Organizational Structure



ABC Study
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Recruitment and Enrollment

Appointment Lists

The ABC database is used to import daily appointment files from the Navy's computer system, which is called CHCS (Composite Health Care Systems). The files from the Navy have been filtered so that we only import well baby appointments for children up to one year in age. Each morning, a printed list of all the well-baby appointments for that day will be given to recruiters as a guide to find potential mothers to recruit from the clinic floor. Sometimes a mother's name will appear blank on the appointment list -- this happens when the Navy's computer does not provide us with that information, and it is ok to find and recruit this mother by looking for her child's name. When both the mother and child are missing from the list, use your (individual) off list appointment sheet to recruit the mom by filling in the necessary information on the form and proceeding with recruitment as usual.

The Appointment List printed out each day includes the following:

- Date in top left corner of appointment sheet
- Child's Appointment Time
- Last 4 digits of Sponsor's SSN (routinely used by the Navy as an I.D. no.)
- Active Duty Status (y/n), if known
- Name of Child
- Child's Date of Birth
- Mother's Name (sometimes not known)
- Study Status (see p. 7 for list of codes & their descriptions)
- Column for recording new recruitment information (recruitment activity / status codes are recorded in this column on a master list at the end of the day; recruiters may use this column on their own sheets to help them keep track of their activity)
- Well-Baby Visit Number (#1-7)
- Weight & Recruiter Initial columns (these are recorded on the master list at the end of the day)
- Freeman Sullivan ID number (FSCID)
- Sponsor's Name (the active duty (military) person in family through whom the child is receiving medical coverage)
- Name of Physician (used to identify mothers as they are checking in and to track down moms who have already checked in. Each doctor has 2 rooms, one of which is essentially a waiting room -- it is ok to approach and recruit moms waiting in these rooms)

The Clinic

The general pediatric clinic handles a range of appointment types (sick, ear check, well baby, etc.), and women may be recruited at any of these visits. The appointment list may help target eligible women because the clinic handles appointments for a variety of ages. The appointment list will also alert you to returning participants (follow-up visits). However, the appointment list should just be considered a guideline for clinic activity -- some women will have just made appointments that morning or may not appear on the list for other reasons, and these women should be approached.

The clinic flow has a West-East side order: Mothers check in at the West clinic, wait there for their child's vital signs to be taken, and then are re-seated to wait for the doctor. After seeing the doctor mothers proceed to the East clinic, where procedures are performed (e.g., shots, blood draws, etc.), follow-up appointments are made, and mothers exit the clinic.

Mothers who are enrolled at Balboa but who will be receiving their well-baby care at North Island should be told that they will receive their questionnaires from the clinic staff at North Island, and they should have their weight taken by the clinic staff there. Moms should then turn in the completed questionnaires to their providers (doctors) at North Island, who will return them to us at Balboa.

FSCID Numbers

Women are assigned FSCID numbers when they appear in the database for the first time – this is our (known) group of potential participants. An FSCID number is a unique identification number that remains linked with a woman's name for the duration of the study. When the mother's name is blank (because her name was not provided by the Navy's computer), her name may be manually added into the ABC database and she will then automatically be assigned an FSCID.

All participant questionnaires are marked with FSCID's instead of names in order to maintain confidentiality (although the mother will initially fill out other identifying information on the front page of the questionnaire, which will be detached at FSC).

It is extremely important to remember that the nature of the information we are collecting is highly sensitive and personal, and needs to be treated with discretion and confidence.

Study Status

Different letter codes in the ABC database indicate a mother's recruitment status within the study. These codes are updated in the ABC database after a mother is approached.
The status codes are as follows (the **bolded letter** is used as the study status code on the appointment list):

Not Approached: This initial status is assigned to all mothers upon import into the ABC database from the Navy computer. It indicates that thus far no one from the ABC staff has attempted to recruit this mother.

Participant: Mothers are assigned this status code after they agree to enroll in the study. If you see this code on the appointment list, it means that mother is already a participant and is at the clinic for a follow-up visit.

Qualified: Assigned to mothers who have completed both (1) a baseline or 12 mo. mom take-home questionnaire, and (2) at least one clinic questionnaire from a 2 mo. – 12 mo. visit.

Contact **L**ater: Mothers are assigned this code when they were approached by a recruiter at their baby's previous Well Baby visit. The mother may still be interested in the study, but for whatever reason could not complete the enrollment at her previous visit, when we initially approached her. When you see this code on the appointment list, you should speak with her. This code could be a soft refusal (undecided) or the mother might be interested but didn't have the time to enroll.

Refused: Assigned to mothers who refused to either be screened or enrolled at a previous Well-Baby visit. NOTE: If you speak with a woman who had previously refused and she refuses again, apologize for approaching her a second time and let her know if she becomes interested at a later date to flag a recruiter down.

Ineligible: Mothers who were screened previously, but were ineligible to participate in the study are assigned this code. You do not need to approach these mothers again if they appear on the appointment list.

Disenroll: This code indicates that the mother was formerly a participant but had to drop out of the study for some reason such as moving, transferring, becoming pregnant, or simply wanting to terminate her participation. Do not approach mothers with this status.

Well Baby Appointments

Standard pediatric medical practice involves checking children several times during the first 24 months of life to monitor their growth. Additionally there are several different immunizations administered to children throughout this time. Well Baby appointments are scheduled in conjunction with the immunization protocol. The mandatory 15 minute waiting period following shots frequently allows enough time to complete the enrollment paperwork. It is helpful to let moms know that they should have enough time to complete paperwork without having to stay beyond typical appointment time.

The Appointment List uses a numerical code to indicate the Well Baby appointment type as explained below:

Visit Number	Well Baby Visit
1	3-7 day weight check (note: The baby's height and head circumference are not measured at this time and will be left blank on the questionnaire.)
2	10-16 day visit (referred to as the "two-week check" by clinic staff)
3	2 month visit (immunization shots given)
4	4 month visit (immunization shots given)
5	6 month visit (immunization shots given)
6	9 month visit (no shots, blood drawn)
7	12 month visit (immunization shots given)

Overview of Recruitment Process

Daily Process When Recruiters Arrive for Their Shifts:

Report to the ABC office.

- Punch in time card.
- Check office logbook for updates or messages.
- Change into lab coat (make sure your ABC button is visible).
- Get Daily Appointment List and clipboard.
- Head out to clinic floor with clinic supply bin.

Find a mother whose name appears on the ABC appointment list for a given day.

- Approach a mother.
- Introduce yourself and the ABC study.
- If mother is a *refusal*, ask if you may ask her a few questions for your records.
  - If she agrees, complete the screening form.
  - If she disagrees, thank her for her time.
- If mother is interested in the study, explain what's involved further and go through **screening form** to determine mother's eligibility to be a participant.
  - If she is *not* eligible, complete the screening form and then explain to her that she is ineligible and thank her for her time.
  - If she *is* eligible ask her if she would like to enroll and proceed to the consent form.
    - Explain key points about the **consent form**, have mom sign both copies, witness both copies, and give one copy to mother for her records.
    - Explain and sign the appropriate **medical records release form**.
    - Hand participant **clinic questionnaire** to complete and return.
    - Review questionnaire for completeness.
    - Record mom's **weight and height** on the back of the questionnaire.
    - Alert participant to expect the take-home questionnaire at 2 mos. and 12 mos., and to complete them and return them for payment.
    - Hand mother **participation information sheet, study welcome letter, and infant card**.
    - Thank mother for enrolling.

6 steps involved in successfully recruiting a mother into the ABC Study.

Step 1. Finding a mother to recruit

The following is the regular routine when mothers and babies arrive at the clinic for well baby visits:

West Clinic

- Mother checks-in at front desk.
- Mother and child are seated in the waiting area.
- Child's name is called to have measurements taken.
- Mother and child are re-seated in the waiting area.
- Child's name is called to see the doctor. Often mother is made to wait further in the doctor's exam room.

East Clinic

- Mother and child are seated in the waiting area after seeing the doctor.
- If the child is due for immunizations, child's name is called for immunization shots.
- Mother and child are then asked to sit again in the waiting area. They have to stay in the waiting room after the shots have been administered to ensure that the child does not have any adverse reactions to vaccines.
- Mother exits clinic.

A mother can be in the clinic from 30 minutes up to 2 hours after the time of the appointment. She can be approached for recruitment at any time during her stay at the clinic. Because there are so many different parts to a well baby visit, a recruitment may be interrupted frequently (when the child's name is called). In this situation a recruiter should follow the mother if possible. Otherwise do not waste time waiting for the mother -- instruct her to find you back in the clinic when she is finished, and move on to a new recruitment.

The chances of enrolling mothers are significantly higher if they are approached at the beginning of their visit. Since the enrollment visit can be time-consuming it is important and most efficient to begin the process as soon as possible. It is optimal to locate the mother at the time she first checks into the clinic. Since the times of the appointments are provided on the appointment sheet, you can guestimate as to who will be in the waiting room at a given time. Find a woman with a young child sitting in the waiting room and approach.

Step 2. Approaching and Screening to Determine Eligibility

Given the volume of mothers and children in the clinic, streamlining the screening and consent process is of utmost importance so that as many women as possible can be approached and enrolled.

Step 2a. Approaching mothers:

When approaching a mother, say something such as:

"Hi my name is ___ from the ABC study. Has anyone talked to you about our study yet? The Navy and UC Berkeley are doing a study about new mothers during their baby's first year of life. It's really easy to be a participant. All you would have to do is get weighed at Well Baby visits, when your baby does, and fill out a questionnaire while you're at the clinic. You'll also get $10 each time for filling out two take-home questionnaires. Would you like to hear more?"

You don't need to explain everything to the mother at the initial encounter - say just enough to peak her interest.

Step 2b. Screening:

- If she is interested, then proceed with:
  "What is your name? Let me see if you're on my list. Before I explain the rest of the study details, let me make sure that you are eligible for the study."
  Begin to use the Screening Form to ascertain if the woman is eligible to participate (instructions below).
- If she does not want to enroll at this time, we would still like to account for her. Ask her:
  "Can I ask you a few short questions, so that I can keep our records straight?
  - If she says YES, proceed with the Screening Form.
  - If she says NO, thank her for her time and move onto another mother (after recording the encounter on the screening form).

Step 2c. Eligibility:

A woman is eligible to participate in the study:

1. who delivered a baby within the past 12 months;
2. who can read and speak English;
3. whose child spent fewer than 96 hours (4 days) in the neo-natal intensive care unit;
4. who is <u>not</u> currently pregnant;
5. who intends to continue to bring her baby back to the Naval Medical Center at Balboa or North Island <u>after</u> the newborn Well Baby visits (i.e. 3-7 Day and 10-16 Day visits).
6. whose child is eligible to receive Well-Baby care at the US Naval Medical Center, Balboa Park or North Island. (NOTE: The grandchildren of sponsors can only receive care for the first 45 days of life. Therefore the mothers of those children are ineligible for the study; they are screened out at criteria #5.)

Step 2d. Guidelines for completing the Screening Form

J Record the FSCID in the top right-hand corner. If no FSCID is listed check "NO" and be extra careful to record the last 4 of the sponsor's SSN, the child's first name, and the child's dob. (This mother will need to be recorded on the "Off List Appointment Sheet.")

J Using the boxes at the top of the sheet, check the "screen" box (vs. disenroll) and check the appropriate box to indicate whether the mother is bringing her child in for a well-baby appointment (regular first-year appointment) or an acute appointment (mother bringing in a sick baby).

J Fill out the identification information at the top of the screener (e.g., Sponsor's first name through appointment date). Make sure to fill out <u>all</u> identification information on the screener – we use this information to update the database and appointment records, as well as to fill in missing information.

J Complete the screener questionnaire as follows:

Q1: Check YES if you were able to speak with the mother <u>and</u> obtain answers to the identification questions and question # 5 (the eligibility criteria).

If NO, indicate why you were unable to either approach or screen the mother:

- Check box 1 if the mother is unwilling to speak with you today (e.g., because she is too busy) but is willing to talk to an ABC recruiter at the baby's next appointment.
- Check box 2 if the mother refused to speak with you and is not interested in the study.
- Check box 3 if someone other than the mother brought the baby to the WB appointment (such as father, other family member or friend).
- Check box 4 and explain if there is another reason you were not able to either approach or screen the mother.

Q2: Ask the mother if she is on active duty <u>regardless</u> of what the appointment list indicates. **<u>This is extremely important</u>** - we must ensure that as many active duty mothers enroll as possible. Directly ask *"Are you on active duty?"* rather than *"Is your husband the sponsor?"* because the husband may be the sponsor even if the mother is an active-duty, military woman.

IF YES, ask the mother and record:
- which BRANCH of the military she is in (Army, Navy, Marines, etc.)
- what RANK she is (which can be found on her medical card if available). This question is an important measure of socioeconomic status. A rank is something like E4. Terms such as PO3 ("Petty Officer 3") are rates, not ranks. (The medical card would say E4/P03.) When in doubt, record both #'s.

Q3: Ask the mother how many other children, not including her new baby, she has given birth to: This number does not include abortions or miscarriages. The question is asking about live births.

Q4: Obtain the mother's date of birth.

Eligibility Criteria

Q5: There are 5 eligibility sub-questions, and you should ask the mother all sub-questions listed under question 5, even if you check off a shaded box indicating that a mother is ineligible to participate in the study. When you are finished with all of the sub-questions, then inform the mother that she isn't eligible for the study. The 5 eligibility sub-questions are:

Currently Pregnant? If a woman is currently pregnant, then we can't observe her postpartum weight patterns. To determine this information, you can ask her nonchalantly: *"Is there any chance you're pregnant now?"*

- If she says YES, determine if she has had a medical test or a home pregnancy test.
- If she isn't sure or says something to the effect of "I still haven't had my period," check NO. We need stronger evidence - a positive pregnancy test.

NIC-U? Ask the woman if the baby spent any time in the neonatal intensive care unit. If the woman is anxious about these questions, explain that *"these questions need to be asked of all women."* If the baby was in the NIC-U, determine the length of stay by asking her: *"How many days was your baby in the NIC-U?"*

- If she says 3 days or less, check NO.
- If she says 5 or more days, check YES.
- If she says 4 days, determine how many hours the baby spent in the NIC-U by asking her what time the baby was born and the time that the baby was released. For example, if the baby was born on Monday night and was discharged from the NIC-U on Thursday morning, then the baby spent fewer than 96 hours in it and the mother is eligible to participate.

BIOLOGICAL CHILD ≤ 12 MOS.? The child must fulfill both parts of this question: We can only study women who gave birth to a baby within the past 12 months. If the mother did not give birth to the child, then check NO. To determine this ask her directly. You can be friendly about it by saying: *"I have to ask, but did you give birth to your baby?"* Do not ask: *"Was the child adopted?"* because it may be a sensitive issue or the baby may be a step or foster child.

SPEAKS ENGLISH? If the woman's husband or another person accompanies her to translate into English, check NO. Some women may understand English, but still struggle with it. The questionnaires were designed to be read at about an 8th grade reading level. Use your professional opinion when allowing women to enroll who are borderline in terms of understanding English. Be sure to document it on the screener form after leaving the immediate area of the mom.

CARE AT BALBOA / NORTH ISLAND BEYOND 2 MOS.?

- If the age the mother's baby is 2, 4, 6, 9 or 12 months, check YES, regardless of whether the mother's intends to come back after the day you screen her.
- If the baby is a newborn at his/her 3-7 day or 10-16 day Well Baby visit, ask the mother if she intends to continue to bring her baby to Balboa Medical Center Pediatric Clinic or North Island.
- Check NO, only if she specifically states that the child will not be brought back to these 2 clinics beyond the child's two-week check (10-16 day visit).
- If she says that she will be transferring a few months from now, but will bring the baby back here until she moves, check YES.

IF **any** of the shaded boxes are checked, the mother is not eligible to participate in this study. There are a number of ways to tell her why she can't be part of it, here are a couple:

- "*I'm glad to see that your baby is out of the NIC-U. S/he is so cute, but unfortunately, we can't enroll you. Good luck and congratulations.*"
- "*Congratulations on your pregnancy! Since this study is about moms after the baby comes, we can't enroll pregnant moms because your health patterns are different than other postpartum moms, but we'd be happy to enroll you once your new baby is born.*"

Q6 no longer part of screening form.

Q7: Check whether the baby was delivered at Balboa or not. If NO, record the name of the facility, city, and state where the child was born. If the baby was born at home, indicate the facility at which the mother received prenatal care. This information is used for medical record abstraction purposes; we need to know where the baby was delivered in order to request records from the proper institution.

Q8: Fill in the recruitment status code per the recruiter disposition sheet.
The following are the only codes to be used on screener forms:

1 = respondent refused to be in the study
2 = respondent asked to be contacted later
5 = respondent was ineligible for the study
10 = respondent was enrolled on current day

Q9 not relevant to screening potential participants.

If Mother Chooses to Enroll:

Q10: Obtain current mailing address information
Q11: and current telephone information.

Record your ABC Staff ID in the bottom right hand corner.

Step 3. Obtaining Informed Consent and Signing Medical Release Forms

The consent form is a document which explains to the research participant what the study involves, and it is required in all research studies. Our consent form is a lengthy and complicated military document telling the mothers what the study is about, who is funding it, what participation involves, what the benefits of participation are, etc.

The consent form must be understood, signed by the mother, and witnessed by the recruiter in order for a mother to be enrolled in the ABC study. Mother and recruiter will sign two copies of the consent form -- one for us and one for the mother to keep for her records.

Points about the Consent Form to Cover with Mothers Before they Sign:

- The ABC study is a study about mothers and babies being done by the Navy and UC Berkeley to learn about their health and fitness during the first year postpartum. It is the largest study of its kind ever to be done, with an estimated enrollment of 4,000 mothers.
- Mothers fill out questionnaires and get weighed when their baby comes in for appointments. It's easy -- no extra visits are required.
- There are 2 take-home questionnaires that mothers get paid $10 for completing and returning. (Mothers who enroll when their child is 12 mos. only receive one take-home questionnaire.)
- We measure the mother's height once.
- Mothers sign a form to let us look at their prenatal/pregnancy records to link information from before their baby to "after the baby comes"!
- Participation (or non-participation) doesn't affect mothers' medical benefits or cost anything.
- Participants' answers are kept private; we assign them a special number used only for this study. However, the military says we must say that some information could be added to their medical record -- but we don't expect that to happen. At the moment there are no procedures for doing this.
- There aren't any direct benefits for participating, but it will help military mothers in the future.
- We'll send participants a copy of the results if they want, and to do this we need their permanent address, which will be obtained on the last page of the take-home questionnaires.
- We use their sponsor's SSN to get information from their baby's birth certificate to compare the babies in our study to all babies born in California.

ACTIVE DUTY MOMS:

- Active duty mothers sign a form to let us see their PRT (Physical Readiness Test) results.
- This study is designed especially for active duty mothers, so we really hope they will participate in order to help change military policies concerning postpartum active duty women.

<u>Be sure that both you and the mother</u>

-] Initial and date the bottom of each page of the consent form
-] Sign and print your names and SSN's on the last page (p.6) of the consent form and on the Privacy Act Statement page.

Obtaining Release of Medical and Physical Readiness Test Records

The study consent form states that the participant agrees to sign an additional form releasing her prenatal medical records. If the mother is on active duty, we would also like access to her Physical Readiness Test (PRT) results, as stated in the consent form.

The medical records release form allows women to give us access to both or just one of these sets of records. Two versions of the form exist since some women will transfer to Balboa after delivering their babies somewhere else:

- One (white copy) specifically authorizes the San Diego facility to allow ABC staff to access the mother's and child's records.

- The other version (yellow copy) has a blank line in which the mother or ABC staff person must record the name of the hospital, city, and state in which the baby was born, and is otherwise essentially the same form.

In completing a medical record release, Mom should:
-] Check the appropriate boxes allowing us access to prenatal and/or PRT records.
-] Write in the name of the hospital at which the baby was born if other than Balboa.
-] Write in the Baby's DOB (under prenatal record release section).
-] Print and sign her name, and fill in the date.
-] Fill in her SSN.

ABC staff should:
-] Print and sign name as witness.

Step 3a. Forms to Leave with Mother

After the mother has been screened, consented, and enrolled, give her the following:
- The ABC Welcome Letter
- Participant Information Summary
- Her copy of the Consent form
- Infant card and/or colored card with study information
- Take-home questionnaire if applicable (Baseline or 12-mo. Mom Take-Home Questionnaire)

Briefly explain to her what each item is. If her hands are full, offer to put the items in her baby bag.

Page by page summary of the consent form for ABC recruiters to use as a reference to help them explain the consent form to mothers. Always use key point explanation from p. 15 first, and then provide further explanation upon inquiry of mother.

Page 1:

- Item #1- says that you are being asked to participate in the ABC study and that the study is being done by the Navy along with researchers from UC Berkeley.
- Item #2- says the purpose of the study is to look at changes in women's health and fitness in the first year after having a baby, as well as to look at the health and growth of your baby.

Page 2:

- Item #3-says you can participate up to when your child is one year old - although it's okay if you move before then, or have to miss some visits. It's even okay to participate just today.

- **Item #4- describes what you have to do if you agree to be in the study.** This is:
  1. Have your height measured (once).
  2. Be weighed each time you bring your baby in for a well baby visit.
  3. Fill out a questionnaire at each well baby visit.
  4. Fill out two longer questionnaires at home - one when you start the study (or when your baby is two months old, if you start earlier) and one when your baby is one year old.
  5. Sign a form allowing us to look at your medical records from your pregnancy (and PRT records if you are active duty). We will write down information such as your weights during pregnancy, the weight of your baby at birth and ultrasound reports.
  6. Give us your Social Security Number so we can look at information on your baby's birth certificate
- Item #5- just says we expect 4000 women to be in the study.
- Item #6-states that there aren't any risks you take by being in the study. The only expected burden for you is the time it takes to be weighed and to answer the questions. If any of the questions disturb you, you have the right to skip them.

Page 3:

- Item #7-We hope the knowledge gained will help improve the health of mothers and their infants in the future, although you personally won't receive any direct health benefits for participating.
- Item #8-says that none of the information collected is expected to be entered into your medical records. We will keep your information private, and this describes all the steps we will take to make sure of this. We use a confidential study ID number and lock away the list that links your name to your ID number. Your name will never be published anywhere.

Page 4:

- Item #9-says that if you are hurt directly from being in this study, the Naval Medical Center will treat you.
- Item #10- tells you who to contact if you have questions about the study or your rights as a participant. (But you are welcome to speak to me or any of the other ABC staff as well.)
- Item #11- says that you will not lose any health care benefits if you choose not to be in the study. Also, you have the right to withdraw from the study at any time just by letting us know.
- Item #12- says we also have the right to withdraw you from the study at any time.

Page 5:

- Item #13- says it won't cost you any money to be in the study.
- Item #14-says you understand all of the above and agree to be in the study. Also that we have given you a copy of the "Experimental Subjects Bill of Rights" *(show to mom - last page of consent packet)* which tells you your rights as a subject in a research study.

- Item #15- says we will give you a copy of the results of the study if you ask for one.

Step 4. Obtaining Mother's Height and Weight

The most important piece of information that is collected throughout this study is the weight of the mother. Recruiters will be trained on how to measure weight and height according to the strict guidelines of the study. It is the responsibility of the recruiter to make sure that a participant's weight and height are taken before the participant leaves the clinic.

There are two scales - one in the east clinic and one in the west clinic. Recruiters obtain Mom's height and weight at enrollment. The staff member (Nurse or Corpsman) who obtains baby's measurements should obtain and record returning participant's weight. Weight is taken in kgs. and height is taken in cm. Always document the measurements immediately in the space provided on the back of the questionnaire.

Guidelines for Taking a Mother's Weight:

- Have the participant take off her shoes and coat and put down any purses or heavy bags. If the mother is carrying her child, place the child in the ABC baby seat or have someone else hold the child. Inform the mother that you will be taking her weight and height twice and possibly three times for accuracy.
- Press the ON button on the scale and wait for "0.0" to appear on the display panel.
- Press the KGS. button to change the measurement from LBS. to KGS.
- Have the mother step onto the scale. Wait for her weight to appear on the display and for the scale to beep.
- Record the first weight in the space provided on the back of the questionnaire.
- Ask the mother to step off scale.
- To zero out the scale press either the REWEIGH button or ZERO and wait for "0.0" to appear again.
- Ask the mother to step back onto the scale.
- Record the second weight in the space provided on the back of the questionnaire.
- Look at the two recorded weights. **If they differ by more than ± 0.1 kg, zero out the scale and weigh the mother a third time. If the first two weights do not differ by more than 0.1 kg, stop.**
- After the weight has been obtained and recorded for the final time, if the mother wants to see her weight in pounds, simply press the LBS. button and the weight will change from kgs. to lbs.

Guidelines for Taking a Mother's Height:

- Make sure that her shoes are off.
- Ask her to stand on the scale with her back and heels centered up against the steadiometer (back of stand).
- Tell the mother to stand up straight and take deep breath.
- Slowly slide the bar down until it sits on her head. Make sure that the bar is touching the top of her head. If her hair is up ask her to take it out to get an accurate reading.
- Verify that the mother is comfortable and that the bar is resting evenly on her head.
- Turn the black knob to clamp the bar in place and ask mother to step back.
- Read her height off the black line of the clear plastic tab and record her height in centimeters, to the nearest millimeter, in the first space provided on the back of the questionnaire.
- Unclamp and slide the bar up and ask mother to step back into place in order to measure her height for the second time.
- Look at the two recorded heights. **If they differ by more than ± 0.5 mm, unclamp the bar and measure the mother a third time. If the first two heights do not differ by 0.5 mm, stop.**

Example of where to fill in measurements on the back of the clinic questionnaire:

Mother's Ht. (cms)	Mother's Weight (kgs)	Today's Date (mo/day/yr)
① ___ ___ ___ . ___	① ___ ___ ___ . ___	___ ___ / ___ ___ /___ ___
② ___ ___ ___ . ___	② ___ ___ ___ . ___	
③ ___ ___ ___ . ___	③ ___ ___ ___ . ___	
If ① & ② are the same STOP. If height ① & ② differ by more than ± 5mm, do height ③	If ① & ② are the same STOP. If weight ① & ② differ by more than ± 0.1 kg, do weight ③	

Step 5. Clinic Questionnaires

Participants are asked to complete a clinic questionnaire at each well baby visit and two additional take home questionnaires throughout the study. The questionnaires cover a variety of issues relevant to the health and fitness of both the mother and child including:

1. Health
2. Infant Feeding (Lactation/Formula)
3. Sleep patterns
4. Birth control
5. Work/Active duty service
6. Physical activity
7. Body image concerns
8. Depression
9. Stress
10. Social support
11. Physical Readiness Test
12. Partner issues/Deployment

There are 3 different types of self administered clinic questionnaires, meaning the mother fills them out herself. They are:

Questionnaires	Completed by Mother When
3-7 day clinic questionnaire	She is recruited at her baby's first well baby visit.
10-16 day clinic questionnaire	She is recruited at her baby's two week well baby visit
2-12 month clinic questionnaire	She is recruited at her baby's 2, 4, 6, 9 or 12 month visit

Both the 3-7 day and the 10-16 day questionnaires are much shorter than the 2-12 month questionnaire in order not to overly burden brand-new mothers.

Recruiters should become familiar with the types of questions being asked of the participants as well as the skip patterns in order to catch blank questions when quickly reviewing collected questionnaires. Recruiters should make every effort possible to facilitate the mother's completion of the questionnaire. Using clipboards and having pencils available is helpful. Other things such as offering to hold or distract the baby or her other children can also be employed.

Often times the baby's father accompanies the mother for the visit. Many fathers offer to record the responses for the mother, while she holds the baby. Discourage this by suggesting *"Can Dad hold the baby while you complete the form?"* We want to avoid having the father influence the responses of the mother. If you notice that a woman asks her husband, or if he offers responses, say something to the mother such as, *"We're interested in what you think/feel."* When the mother finishes filling out the survey, the recruiter is responsible for obtaining the questionnaire and quickly reviewing it as well as ensuring that the mother is weighed before she leaves the clinic.

If Mom does not bring in baby for appointment, you can ask Dad (or other relative), *"Is mom here? She is part of a study we're doing. Could you please take this questionnaire and return envelope for her to complete at home and mail back to us?"* These questionnaires are the same as the 2-12 mo. clinic questionnaire, but include a self-weight sticker on the front page, a cover letter explaining to mom how to weigh herself at home, and a return envelope. These pre-made packages will be available to hand out. ***Please note: These are* not *the same as the Take-Home questionnaires (i.e., the participant will not be paid for this questionnaire).***

STEP 5A. TAKE-HOME QUESTIONNAIRES

Take home questionnaires should be handed out in the clinic, with postage-paid return envelopes, as follows:

Visit No.	Participant Status	Take-Home Questionnaire to Hand Out
3-6	P	Baseline (gold)
7	P	12 Mo. Mom (ivory)
7	Q	Follow-up (pink)

When handing out take-home questionnaires, ask Mom if she has recently received, completed, and returned that particular take-home questionnaire (Baseline, 12 Mo. Mom, and Follow-Up). We are trying to minimize the duplicates -- moms should fill out only one of each type (e.g., Mom may fill out two take-home questionnaires, but they should be a Baseline and Follow-up, not 2 Baselines). However, the most important thing is to ensure that take-home questionnaires get completed and returned, so give Mom a take-home questionnaire if she is unsure whether she already completed and returned it.

When handing out the take-home questionnaires, alert mothers to the fact that they will get paid $10 when they return the questionnaires and that the answers are extremely important. And as always, thank them for their time.

Step 6. Obtaining Baby Measurements

Baby measurements should ideally be collected at the time the child is actually measured. As a back up, they can be obtained from the child's chart either by the corpsman or the recruiter. They should be recorded on the back of the clinic questionnaire.

Example of where baby measurements should be recorded:

Baby's Length (cms)	Baby's Weight (kgs)	Baby's Head Circumference (cms)
___ ___ . ___	___ . ___ ___	___ ___ . ___

Corpsmen and other medical professionals are not expected to go out of their way to do additional measurements specifically for the ABC Study. At the 3-7 day well baby visit the baby's length and head circumference are not always collected. If a measurement is not collected simply place a line through that part on the questionnaire.

Although it is important to obtain complete data on as many participants as we can, we don't want to waste time looking for baby charts when we could be recruiting a new mother into the study. The following order should be followed to obtain baby measurements:

- If you catch a mother at the beginning of her visit, before her baby is measured, have the corpsman record the baby measurements on the ABC questionnaire as they measure the baby.

- If an enrollment begins after the baby was already measured, you may obtain oral measurements from the mother and record them on the back of the questionnaire. Be sure to indicate the units. The mother will usually remember the weight in pounds, not kilograms.

- If the mother doesn't remember her baby's measurements, take 5 minutes maximum to track down the chart in the clinic and record the measurements on the back of the questionnaire. You will be given a tour of where to locate the chart during training. Remember that your main priority is to recruit new mothers into the study, so don't get stuck looking for a chart.

- If you locate a mother's chart who you have just enrolled, you may place an "ABC" study sticker on the chart. Otherwise, at the end of the day add the new mothers whom you recruited to the "Needs Sticker" list and Cathy will add stickers to the new participants' files.

Materials that make up a complete recruitment packet:

- ABC Study Brochure
- Infant Card
- Screening Form
- Consent Form - 2 copies
- Release Form - version for San Diego NMCSD & elsewhere
- Participation Summary for Moms
- Welcome letter from Barbara Abrams for Moms
- Clinic questionnaire

Overview of the Follow-Up Process

In addition to approaching, screening and recruiting new participants, the other important aspect of a recruiters job is to be a point of contact with moms who are already enrolled in the study. Not only is it imperative that we approach every potential participant who comes into the clinic, it is equally necessary to talk with participants who have already been enrolled and make sure we are reminding them to turn in their questionnaires and get weighed. This follow-up data is a crucial part of the study as we are attempting to not only enroll participants, but also track them over time to gain a greater understanding of the pattern of postpartum weight change. Maintaining contact and having a rapport with these participants improves this follow-up rate.

The follow-up process for the enrolled participants depends on the same Participant Tracking System used for recruiting mothers. "Follow-up appointments" refer to all appointments by mothers already enrolled in the ABC study. They are identified on the daily Master List of appointments (a "participant" code appears instead of a "not approached" code). Study staff insert study questionnaires into each infant's medical record so that when the mother checks her child in with the pediatrics clinic staff, they can hand her a clinic questionnaire to begin filling out. Participants are identified by neon ABC stickers affixed to the infant's medical record if the participant does not identify herself. When there is no medical record, affix the sticker to the ATS Form that is placed in the provider's folder.

Follow-up is accomplished with the assistance of Navy clinic personnel, particularly the check-in clerks and the corpsmen, in conjunction with the ABC study staff. Check-in clerks have been trained to give each ABC participant the study questionnaire and an ABC sticker to wear. The stickers on the mother or the sticker on the infant's chart ("Weigh ABC Mom") reminds the corpsmen to weigh the mother and record her weight on the back of the questionnaire. He also reminds her to complete the questionnaire and drop it in the ABC drop box or return it to study staff. The stickers also alert study staff that the woman is already a participant and to therefore focus on follow-up data rather than recruitment. Whenever study staff are not involved in recruitment, they are actively working with women to ensure that they complete their follow-up visits.

We have recently implemented a procedure whereby the corpman writes the mother's weight on the back of her questionnaire and also next to the "Weigh ABC Mom" Sticker in the infant's chart. In the event that the mom fails to turn in her questionnaire, we will have her data in a second place on clinic premises. Twice weekly, study staff reconcile Clinic Questionnaires received with actual visits. They code the master lists according to this reconciliation. If a participant has not turned in a Clinic Questionnaire or if a weight is missing, recruiters get the information from the infant's chart.

The A B C Participant Tracking Form Well ☐ acute ☐ LISTED: YES ☐1 FSCID: 6 2 8 _____
Screen ☐1 Disenroll ☐2 NO ☐2

Sponsor's First Name:	Sponsor's Last Name:	Sponsor's SSN: ___-___-____
Child's First Name:	Child's Last Name:	Child's Birth Date: Mo./Day/Yr. ___/___/___
Mother's First Name:	Mother's Last Name:	Appointment Date: Mo./Day/Yr. ___/___/___

1. Mother screened: YES ☐1 NO ☐2 If NO: ☐1 Declined-contact later
☐2 Declined-don't approach again
☐3 Father/other person brought child
☐4 Other: _____

2. Mother's Status: Active Duty ☐1 Dependent ☐2 Neither ☐3 (NOT ELIGIBLE)
→ If Active duty: Branch: _____
→ If Active Duty: Rank: _____

3. Number of Other Births: ☐

4. Mother's Birth Date: ___/___/___

5

Mother is currently pregnant	YES ☐1	NO ☐2
Child spent > 96 hours (4 days) in the neo-natal intensive care unit	YES ☐1	NO ☐2
Biological child who is ≤ 12 months old	YES ☐1	NO ☐2
Mother reads and speaks English	YES ☐1	NO ☐2
Well Baby Care beyond 3-7 or 10-16 days to be obtained at Balboa	YES ☐1	NO ☐2

If any of the shaded boxes are checked, STOP. Mother is NOT ELIGIBLE.

7. Balboa Delivery: YES ☐1 NO ☐2 If NO: Name and location of birth hospital:
Name: _____
City, State: _____

8. Recruitment Status Code: ☐

9. Disenrolled Status Code: ☐ 1= Transferred. NOTE: obtain new mailing address below
2= Refused; 3= Pregnant; 4= Other

9a. Reason: _____

10. Mailing Address:

11. Telephone Number:

FSC/SF office use only: a) Consent ☐ b) Release ☐ c) Clinic Questionnaire ☐ d) Weight ☐ e) Height ☐

ABC STAFF ID# ___

Off list Appointment Sheet *Date*_____

Child's name	DOB	Mom's name	Weight #2	Initials	Status	Dispo code	FSCID# or SSN

1 Refused 2 Contact Later 3 NS/Cancel 4 Missed during staff hours 5 Ineligible 7 Q, no weight, called mom 8 Followup complete
10 Enrollment 11 Disenroll 12 Other than mother 14 Missed after hours 16 Not well baby 18 Q sent home with other than mother

Daily Totals

Your Name	Hours worked	Enrollments	Follow-ups (wt taken)	Screened

Off list Appointment Sheet (Follow-up only)

*Date*_____

Child's name	DOB	Mom's name	Weight #2	Initials	Status	Dispo code	FSCID# or SSN

1 Refused 2 Contact Later 3 NS/Cancel 4 Missed during staff hours 5 Ineligible 7 Q, no weight, called mom 8 Followup complete
10 Enrollment 11 Disenroll 12 Other than mother 14 Missed after hours 16 Not well baby 18 Q sent home with other than mother

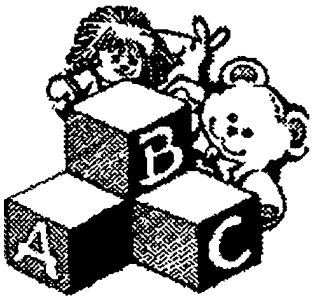
Daily Totals

All Staff	Hours worked	Enrollments	Follow-ups (wt taken)	Screened	Cumulative Enrolled

Official Use Only: FSCID 628 ___ ___ ___ ___ ___

The A B C Study

"After the Baby Comes"



2-12 Month

Clinic Questionnaire for Moms

Please do the following today:

- ❑ Get weighed.
- ❑ Fill out the questionnaire.
- ❑ Return your questionnaire to the ABC staff, office, or drop box.

The information on this page is for tracking purposes only. To protect your privacy, this page will be separated from your answers before processing.

Sponsor's SSN: ___ ___ ___ – ___ ___ – ___ ___ ___ ___	
Baby's first name:	**Baby's date of birth:** ___ / ___ / ___
Your full name:	
Change of Address:	

Official Use Only: FSCID 628 _____

The ABC Study

"After the Baby Comes"

2, 4, 6, 9 and 12 Month Well-Baby Questionnaire for Moms

1. **Which Well-Baby visit are you here for today?**

❑3	❑4	❑5	❑6	❑7	❑8
2 month Well Baby	4 month Well Baby	6 month Well Baby	9 month Well Baby	12 month Well Baby	Other Type of Visit

2. **How would you describe your health during the past 7 days?**

❑1	❑2	❑3	❑4
Excellent	Good	Fair	Poor

3. **During the past 7 days, what kind of milk has your baby been fed?**

- ❑1 Breast milk only *(This includes pumped breast milk in a bottle.)*
- ❑2 Mostly breast milk and some infant formula/milk
- ❑3 About half of both breast milk and infant formula/milk
- ❑4 Mostly infant formula/milk and some breast milk
- ❑5 Infant formula/milk only *(and no breast milk)* → *GO TO QUESTION 5*

4. **If you are breast feeding, during the past 7 days, on a typical night between 11:00PM and 7:00AM, how many times did you wake up to breast feed the baby?**

_____ *times (if none, enter "0")*

5. **During the past 7 days, what was the longest amount of continuous sleep you had?** *(Include naps and sleep during the day as well as at night.)*

_____ *hours*

6. **During the past 7 days, on a typical night, how many times did your baby wake you up, even if you didn't get out of bed?** *(This includes breast feeding times.)*

_____ *times per night (if none, enter "0")*

7. **During the past 7 days, was your baby fed any of the following foods?** *(check all that apply)*

- ☐ a Cereals
- ☐ b Fruits or vegetables *(not including juices)*
- ☐ c Meats
- ☐ d None of the above

8. **Since your baby's last Well-Baby appointment, has s/he been hospitalized?**

- ☐ 1 Yes
- ☐ 2 No

9. **Since your baby's last Well-Baby appointment, has your baby been seen by a developmental specialist?**

- ☐ 1 Yes
- ☐ 2 No

10. **Have you had your menstrual period since your baby was born?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 12*

11. **<u>If you have had your period</u>, what was the first day of your last menstrual period?**

_____ / _____ / _____
Month *Day* *Year*

12. **Are you currently pregnant?**

- ☐ 1 Yes → *IF YES, GO TO QUESTION 14*
- ☐ 2 No
- ☐ 8 Not Sure

13. **<u>If you are NOT pregnant,</u> which of the following types of birth control or contraceptives are you currently using:**

- ☐ 1 Oral contraceptives *(The Pill)* ➔ 13a **What brand?** _____
  Check box if don't know brand ☐ 8
- ☐ 2 Depo-Provera shots
- ☐ 3 Norplant *(a rod that is inserted into your arm)*
- ☐ 4 Condoms, Diaphragm, Cervical Cap or any other barrier method
- ☐ 5 Something else
- ☐ 6 I'm not using birth control right now
- ☐ 7 Tubes tied or hysterectomy

14. **Please indicate your work status during the last work week:**

- ☐ 1 I worked at a job *(for pay or as a volunteer)*
- ☐ 2 I went to school
- ☐ 3 I was on maternity leave ➔ *GO TO QUESTION 18*
- ☐ 4 I'm not employed right now ➔ *GO TO QUESTION 18*
- ☐ 5 I'm on another type of leave/vacation ➔ *GO TO QUESTION 18*

15. **During the past 7 days, how many TOTAL HOURS did you spend at school or work?**
(Example: Worked 2 days for 8 hours a day = 16 work hours,
and went to school 1 day for 3 hours = 3 school hours.
16 + 3 = 19 total hours)

_____*total hours*

16. **During the past 7 days, how many DAYS did you spend at school or work at a job that required walking, carrying or lifting heavy loads?** *(Active Duty Women: include physical training or "PT")*

_____ *days*

17. **During the past 7 days, how many HOURS PER DAY did your school or job require walking, carrying, lifting heavy loads** *(Active Duty Women: include physical training or "PT")*

_____ *hours/day (if none, enter "0")*

18. **During the past 7 days, how many times did you participate in any sports or exercise?**

Number of times in 7 days = _____ *times (if none, enter "0")*

19. **During the past 7 days, other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time** *(to do errands or get to places)***?**

Number of times in 7 days = _____ *times (if none, enter "0")*

20. **During the past 7 days, how many times did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

Number of times in 7 days = _____ *times (if none, enter "0")*

21. **During the past 7 days, has anything interfered with your ability to exercise?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 23*

22. **<u>If yes,</u> please check all of the following that have interfered with your ability to exercise?**

- ☐ a I was too tired
- ☐ b I didn't have adequate child care
- ☐ c It was too expensive
- ☐ d I was injured or ill
- ☐ e I don't enjoy exercising
- ☐ f There's no place to go exercise
- ☐ g The neighborhood isn't safe
- ☐ h I didn't have enough time
- ☐ i It's too soon after my baby was born
- ☐ j Another reason: *Please explain below:*

_____

23. **During the past 7 days, how often have you felt depressed?**

☐ 1	☐ 2	☐ 3	☐ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

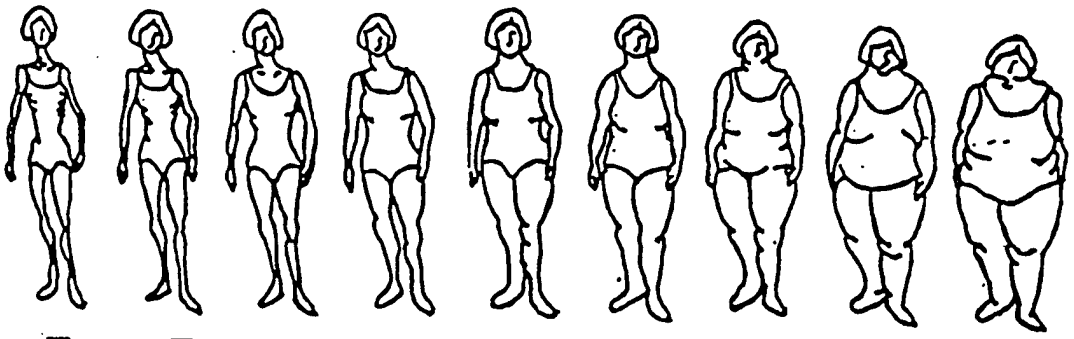
24. **During the past 7 days, which of the following things did you do to control or lose weight?** *(check all that apply)*

- ☐ a Ate less food
- ☐ b Followed a low calorie diet
- ☐ c Skipped meals
- ☐ d Fasted for at least one day
- ☐ e Participated in organized weight loss programs *(example: Weight Watchers, Jenny Craig ,etc)*
- ☐ f Participated in military-sponsored weight loss programs
- ☐ g Avoided junk foods *(examples: sweet or salty snacks, fast food, candy, etc.)*
- ☐ h Used herbal medications
- ☐ i Hypnosis, biofeedback, etc.
- ☐ j Relaxation, visualization, meditation, or stress reduction techniques
- ☐ k Psychotherapy or behavior modification
- ☐ l Received nutrition counseling from a dietitian or nutritionist
- ☐ m Received nutrition counseling from another health care provider
- ☐ n Smoked cigarettes
- ☐ o Meal replacements *(example: SlimFast)*
- ☐ p Took weight loss pills *(over-the-counter or prescription)*
- ☐ q Took laxatives to lose weight
- ☐ r Took diuretics or water pills
- ☐ s Intentionally vomited after eating
- ☐ t Used low calorie sweeteners *(examples: Equal, Sweet-N-Low, NutraSweet, etc.)*
- ☐ u Drank diet soft drinks
- ☐ v Bought low fat foods *(examples: low-fat salad dressing, low-fat ice-cream or low-fat cookies, etc)*
- ☐ w Liposuction
- ☐ x Tried to be more physically active
- ☐ y I worried but did nothing
- ☐ z Did nothing

25. **Currently, do you think you are ...**

❑ 1	❑ 2	❑ 3	❑ 4
Underweight	Just about the right weight	A little overweight	Very overweight

26. **Today, you look most like:**



❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9
A	B	C	D	E	F	G	H	I

27. **During the past 7 days, how often did you worry about your weight?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

28. **During the past 7 days, how often did you worry about your body shape?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

29. **During the past 7 days, how often were you concerned about how much you ate to lose or control your weight?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

30. **During the past 7 days, how often did you worry about your appearance?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

31. **Having a baby adds a lot of responsibilities to the lives of mothers. During the past 7 days, how often have you felt stressed?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

32. **During the past 7 days, how often have you felt stress or concern about child care for your baby?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

33. **Do you currently have a spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 41, page 8*

34. **How satisfied are you with your relationship with your spouse/partner?**

❑ 1	❑ 2	❑ 3	❑ 4
Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

35. **Is your spouse or partner <u>currently</u> living with you at least 5 nights a week?**

❑ 1 Yes → *IF YES, GO TO QUESTION 37*
❑ 2 No

36. **<u>If no,</u> has your spouse or partner been deployed during the past 7 days?**

❑ 1 Yes → *IF YES, GO TO QUESTION 39*
❑ 2 No

37. **Are you getting help at home with taking care of your baby and household chores from your spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 39*

38. **<u>If yes</u>, do you feel that you are getting** ***(from spouse or partner)***

❑ 1	❑ 2	❑ 3
As much help as you need	Some help , but not enough	Just a little help

39. **Are you getting <u>emotional support</u> as a mother of a new baby from your spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 41*

40. **<u>If yes</u>, do you feel that you are getting** ***(from spouse or partner)***

❑ 1	❑ 2	❑ 3
As much support as you need	Some support, but not enough	Just a little support

41. **Are you getting help at home with taking care of your baby and household chores from your family, friends or from paid help?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 43*

42. **<u>If yes</u>, do you feel that you are getting** ***(from your family, friends or from paid help)***

☐ 1	☐ 2	☐ 3
As much help as you need	Some help , but not enough	Just a little help

43. **Are you getting <u>emotional support</u> as a mother of a new baby from your family and friends?**

☐ 1 Yes
☐ 2 No → *IF NO, GO TO QUESTION 45*

44. **<u>If yes</u>, do you feel that you are getting** ***(from your family, friends or from paid help)***

☐ 1	☐ 2	☐ 3
As much support as you need	Some support, but not enough	Just a little support

45. **Do you have enough money to pay your bills this month?**

☐ 1 Yes
☐ 2 No
☐ 8 Not Sure
☐ 9 Decline

The following questions are for ACTIVE DUTY WOMEN only.
If you are not active duty, please STOP here.
Thank you!

46. **How concerned are you about taking your next physical readiness test?**

☐ 1 Not at all concerned
☐ 2 Somewhat concerned
☐ 3 Very concerned
☐ 4 Extremely concerned

47. **What do you think the results of your next physical readiness test will be?**

- ☐ 1 I expect to pass
- ☐ 2 I will probably pass
- ☐ 3 I'm not sure if I'll pass
- ☐ 4 I don't expect to pass
- ☐ 5 I'm not sure how I'll do

48. **How much weight do you need to lose to be within your weight standard?**

_____ *pounds (if none, enter "0")*

☐ 888 Not Sure

49. **Does your <u>current</u> duty assignment have Physical Training *(PT)*?**

- ☐ 1 Yes
- ☐ 2 No → ***STOP. Thank you!***

50. **Is the Physical Training *(PT)* for your <u>current</u> duty assignment mandatory or voluntary?**

- ☐ 1 Mandatory
- ☐ 2 Voluntary

51. **Is PT done ....**

- ☐ 1 As part of a group
- ☐ 2 Individually
- ☐ 3 Both

52. **For your <u>current</u> duty assignment, is time allotted during the workday for PT?**

- ☐ 1 Yes
- ☐ 2 No → ***STOP. Thank you!***

53. **How many days per week are you expected to do PT?**

_____ *days (if none, enter "0")*

54. **How long are you expected to do PT each time you do it?**

_____ *minutes (if none, enter "0")*

ACTIVE DUTY WOMEN please STOP here.
Thank you!

Official Use Only: FSCID 628 ___ ___ ___ . ___ ___

Do not complete this part - for official use only.

Official personnel complete this part: **Medical Staff Initials** ___ ___ ___

55. Baby's Length (cms)

___ ___ . ___

56. Baby's Weight (kgs)

___ ___ . ___ ___

57. Baby's Head Circumference (cms)

___ ___ . ___

58. Mother's Ht. (cms)

① ___ ___ ___ . ___

② ___ ___ ___ . ___

③ ___ ___ ___ . ___

If ① & ② are the same STOP. If height ① & ② differ by more than ± 5mm, do height ③

59. Mother's Weight (kgs)clinic

① ___ ___ ___ . ___

② ___ ___ ___ . ___

③ ___ ___ ___ . ___

If ① & ② are the same STOP. If weight ① &② differ by more than ± 0.1 kg, do weight ③

60. Today's Date (mo/day/yr)

___ ___ / ___ ___ / ___ ___

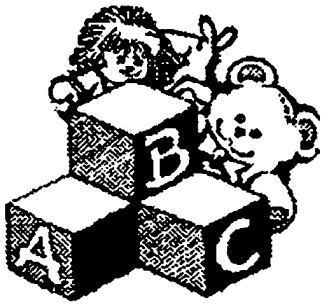
61. Mother's Weight (lbs)

___ ___ ___ . ___ pounds

Official Use Only: FSCID 628 ___ ___ ___ ___ ___

The A B C Study

"After the Baby Comes"



Baseline

Take-Home Questionnaire for Moms

Thank you for taking the time to complete this questionnaire

- The information on this page is for tracking purposes only
- To protect your privacy, the lower half of this page will be separated from the questionnaire before processing
- Please complete the following:

Sponsor's SSN: ___ ___ ___- ___ ___- ___ ___ ___ ___	
Baby's first name:	**Baby's date of birth:** ___ / ___ / ___
Your full name:	

- Answer all the questions on the following pages as instructed
- There are no right or wrong answers - we are interested in how you and your baby are doing
- **Please complete this questionnaire in the next few days and return it to our San Francisco office using the enclosed postage-paid envelope**
- You will be mailed a check for **$10** approximately two weeks after we receive your completed questionnaire

Thank you! - Continue to next page ⇨

1. **Today's date:** ____ / ____ / ____

2. **Not including your new baby, how many <u>other</u> children do you have?** (*Include biological, adopted, foster and step children who live with you at least 5 days a week.*)

   Number of children = _____ *(if none, enter "0" and GO TO QUESTION 4)*

3. **How many of these other children under the age of 5?**

   Number of children under 5 years old = _____ *(if none, enter "0")*

4. **How many times in your life have you lost at least 10 pounds as a result of dieting and/or exercise?** *(This should only be weight loss not related to a pregnancy.)*

   ☐1 Once ☐2 twice ☐3 3 times ☐4 4 times ☐5 5-10 times ☐6 10-20 times ☐7 21 or more

   ☐8 Never → *IF NEVER, GO TO QUESTION 6*

5. **How many times in your life have you gained <u>all</u> of the weight back?** *(Do not include weight gained during pregnancy)*

   ☐1 Once ☐2 twice ☐3 3 times ☐4 4 times ☐5 5-10 times ☐6 10-20 times ☐7 21 or more

   ☐8 Never

6. **<u>ACTIVE DUTY WOMEN ONLY:</u> When was the last time you took a Physical Readiness Test?**
   (Please give the month and year in the space provided.)

   _____ / _____
   Month *Year*

7. **<u>ACTIVE DUTY WOMEN ONLY:</u> What was the result of your last Physical Readiness Test?**

   ☐1 Fail ☐2 Good ☐3 Excellent ☐4 Outstanding

For the following questions, think back to when you were pregnant with your new baby

8. **During the <u>first trimester</u> *(0-12 weeks)*, how often did you participate in any sports or exercise?**

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

9. **During the <u>first trimester</u> *(0-12 weeks)*, other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time *(to do errands or get to places)*?**

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

10. **During the <u>first trimester</u> *(0-12 weeks)*, how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

11. **During the <u>first trimester</u> *(0-12 weeks)*, how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
Never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

12. **During the <u>second trimester</u> *(13-28 weeks)*, how often did you participate in any sports or exercise?**

❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
Never or less than once a month	1 - 3 times a <u>month</u>	Once a week	2 - 3 times a <u>week</u>	More than 3 times a week

13. **During the second trimester *(13-28 weeks)*, other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time *(to do errands or get to places)*?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

14. **During the second trimester *(13-28 weeks)*, how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

15. **During the second trimester *(13-28 weeks)*, how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

16. **During the third trimester *(29 weeks - delivery)*, how often did you participate in any sports or exercise?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

17. **During the third trimester *(29 weeks - delivery)*, other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time *(to do errands or get to places)*?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

18. **During the third trimester *(29 weeks - delivery)*, how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

19. **During the third trimester *(29 weeks - delivery)*, how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

For the following questions, think about the past 7 days:

20. **Please indicate your work status during the past 7 days:**

- ☐ 1 I worked at a job *(for pay or as a volunteer)*
- ☐ 2 I went to school
- ☐ 3 I was on maternity leave → *GO TO QUESTION 34, page 7*
- ☐ 4 I'm not employed right now → *GO TO QUESTION 34, page 7*
- ☐ 5 I'm on another type of leave/vacation → *GO TO QUESTION 34, page 7*

21. **How many hours did you work or spend at school during the past 7 days?**

_____ ***hours***

22. **During the past 7 days, how many DAYS did you work at a job that required walking or carrying or lifting heavy loads or Physical Training *(PT – for active duty women)*?**

_____ ***days***

23. **On what date did you return to work or school?** _____ / _____ / _____
Month *Day* *Year*

24. **What is your job title/rate?**

_____

25. **Please list the three activities that you spend the most time doing at your job or school?**

a) _____

b) _____

c) _____

	Never	Seldom	Sometimes	Often	Always
26. In the past 7 days, at work I sat	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. In the past 7 days, at work I stood	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28. In the past 7 days, at work I walked	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
29. In the past 7 days, at work I lifted heavy loads	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. In the past 7 days, at work I sweated from exertion	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. In the past 7 days, at the end of a day I was physically tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. In the past 7 days, at work I did Physical Training *(PT for active duty)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

33. Compared to women my own age, I think my job's activities are <u>physically</u>...

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
much heavier	heavier	as heavy	lighter	much lighter

34. **Please check all of the physical activities you have participated in during the past 7 days. Also indicate how many times you did these activities and the amount of time you spent doing them.**

	Activity	Check here if you did this	Check here if done as part of Active Duty Physical Training	Number of times you did this activity during the past 7 days?	On **average**, how long do you spend doing this activity **each time you do it?**
35.	Riding a bicycle for exercise	☐a	☐b	___ times	_____ hours _____ min.
36.	Swimming	☐a	☐b	___ times	_____ hours _____ min.
37.	Walking while pushing the baby in a stroller or carrying the baby in a front or back pack	☐a	☐b	___ times	_____ hours _____ min.
38.	Walking without the baby for exercise	☐a	☐b	___ times	_____ hours _____ min.
39.	Jogging or running	☐a	☐b	___ times	_____ hours _____ min.
40.	Aerobic exercise classes *(step, jazzercize, etc.)*	☐a	☐b	___ times	_____ hours _____ min.
41.	Postpartum or "baby and me" type classes	☐a	☐b	___ times	_____ hours _____ min.
42.	Yoga or stretching	☐a	☐b	___ times	_____ hours _____ min.
43.	Weight or muscle strengthening or calisthenics	☐a	☐b	___ times	_____ hours _____ min.
44.	Lifting weights	☐a	☐b	___ times	_____ hours _____ min.
45.	Exercise tapes or videos	☐a	☐b	___ times	_____ hours _____ min.
46.	Gardening	☐a	☐b	___ times	_____ hours _____ min.
47.	Using aerobic exercise equipment *(such as stairmaster, rowing machines, Nordic track, etc.)*	☐a	☐b	___ times	_____ hours _____ min.
48.	Another activity *(Please explain)* _____	☐a	☐b	___ times	_____ hours _____ min.

49. **During the past 7 days, has anything interfered with your ability to exercise?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 51*

50. **<u>If yes,</u> please check all of the following that have interfered with your ability to exercise?**

- ☐ a I was too tired
- ☐ b I didn't have adequate child care
- ☐ c It was too expensive
- ☐ d I was injured or ill
- ☐ e I don't enjoy exercising
- ☐ f There's no place to go exercise
- ☐ g The neighborhood isn't safe
- ☐ h I didn't have enough time
- ☐ i It's too soon after my baby was born
- ☐ j Another reason: *Please explain below*

_____

51. **How many minutes do you walk and/or ride a bicycle per day to and from work, school and shopping?** *(Do not include any time reported in #34).*

- ☐ 1 Less than 5 minutes
- ☐ 2 5 to 15 minutes
- ☐ 3 15 to 30 minutes
- ☐ 4 30 to 45 minutes
- ☐ 5 More than 45 minutes

52. **What is your usual pace when you walk?**

- ☐ 1 Casual strolling – *(slower than 2 miles per hour or fewer than walking 4 city blocks in ten minutes)*
- ☐ 2 Neither fast nor slow *(about 2-3 miles per hour or 4-6 city blocks in ten minutes)*
- ☐ 3 Fairly brisk - faster *(about 3-4 miles per hour or 6-8 city blocks in ten minutes)*
- ☐ 4 Very brisk - very fast *(more than 4 miles per hour or more than 8 city blocks in ten minutes)*

For the following questions, think about how you felt during the past 7 days:

	Rarely or none of the time	Some or a little of the time	More than half of the time, but not most of it	Most or all of the time
53. During the past 7 days, I was bothered by things that don't usually bother me.	☐ 1	☐ 2	☐ 3	☐ 4
54. During the past 7 days, I did not feel like eating; my appetite was poor.	☐ 1	☐ 2	☐ 3	☐ 4
55. During the past 7 days, I felt I could not shake off the blues even with help from my friends.	☐ 1	☐ 2	☐ 3	☐ 4
56. During the past 7 days, I felt that I was just as good as other people.	☐ 1	☐ 2	☐ 3	☐ 4
57. During the past 7 days, I had trouble keeping my mind on what I was doing.	☐ 1	☐ 2	☐ 3	☐ 4
58. During the past 7 days, I felt depressed.	☐ 1	☐ 2	☐ 3	☐ 4
59. During the past 7 days, I felt that everything I did was an effort.	☐ 1	☐ 2	☐ 3	☐ 4
60. During the past 7 days, I felt hopeful about the future.	☐ 1	☐ 2	☐ 3	☐ 4
61. During the past 7 days, I thought my life had been a failure.	☐ 1	☐ 2	☐ 3	☐ 4
62. During the past 7 days, I felt fearful.	☐ 1	☐ 2	☐ 3	☐ 4
63. During the past 7 days, my sleep was restless.	☐ 1	☐ 2	☐ 3	☐ 4
64. During the past 7 days, I was happy.	☐ 1	☐ 2	☐ 3	☐ 4
65. During the past 7 days, I talked less than usual.	☐ 1	☐ 2	☐ 3	☐ 4

	Rarely or none of the time	Some or a little of the time	More than half of the time, but not most of it	Most or all of the time
66. During the past 7 days, I felt lonely.	❑ 1	❑ 2	❑ 3	❑ 4
67. During the past 7 days, people were unfriendly.	❑ 1	❑ 2	❑ 3	❑ 4
68. During the past 7 days, I enjoyed life.	❑ 1	❑ 2	❑ 3	❑ 4
69. During the past 7 days, I had crying spells.	❑ 1	❑ 2	❑ 3	❑ 4
70. During the past 7 days, I felt sad.	❑ 1	❑ 2	❑ 3	❑ 4
71. During the past 7 days, I felt that people disliked me.	❑ 1	❑ 2	❑ 3	❑ 4
72. During the past 7 days, I could not get going.	❑ 1	❑ 2	❑ 3	❑ 4

For the following questions, think back to when you were pregnant with your new baby:

73. **<u>Before</u> you were pregnant, did you have diabetes?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 75*

74. **Did you take insulin for it?**

❑ 1 Yes
❑ 2 No

75. **Did you have diabetes at any time during your pregnancy?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 77*

76. **Did you take insulin for it?**

- ☐ 1 Yes
- ☐ 2 No

77. **When you were pregnant, did a health care provider** *(doctor, nurse, midwife, etc.)* **tell you that you had hypertension, high blood pressure or pre-eclampsia?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 79*

78. **During which part of your pregnancy did you have this condition?**

- ☐ 1 During the first half *(1-20 weeks)*
- ☐ 2 During the second half *(21 weeks - delivery)*
- ☐ 3 During the entire pregnancy

79. **Was this baby born by cesarean section (c-section)?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 81*

80. **<u>If yes,</u> was this your first cesarean delivery?**

- ☐ 1 Yes
- ☐ 2 No

81. **Did you get your tubes tied after giving birth to this baby?**

- ☐ 1 Yes
- ☐ 2 No

82. **What was your weight before you got pregnant with this baby?**

_____ *pounds*

83. **<u>At that weight</u>, did you think you were...**

☐ 1	☐ 2	☐ 3	☐ 4
Underweight	just about the right weight	a little overweight	very overweight

84. **It's both natural and expected to gain weight during pregnancy. How satisfied are you with the amount of weight that you gained when you were pregnant?**

☐ 1	☐ 2	☐ 3	☐ 4
Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

85. **How much weight did you gain during your pregnancy?**

_____ ***pounds***

86. **How much weight were you advised to gain by your health care provider** ***(either your doctor, nurse, physician's assistant or midwife)*****?**

_____ ***pounds*** ☐ 99 not advised ☐ 88 not sure

87. **During your pregnancy, did anyone tell you that you were <u>not</u> gaining enough weight?**

☐ 1 Yes

☐ 2 No → *IF NO, GO TO QUESTION ~~90~~ 89*

88. **<u>If yes</u>, who told you this?** ***(please check all that apply)***

☐ a spouse or partner	☐ f midwife
☐ b friend	☐ g nurse/nurse practitioner
☐ c mother	☐ h nutritionist or dietitian
☐ d other family member	☐ i WIC staff
☐ e doctor	☐ j commanding officer

89. **Which of the following things did you do to try to gain more weight during your pregnancy?** *(please check all that apply)*

- ☐ a Worried but did nothing
- ☐ b Got nutrition counseling from a dietitian or nutritionist
- ☐ c Got nutrition counseling from another health care provider
- ☐ d Quit smoking cigarettes
- ☐ e Ate more food at meals
- ☐ f Added more meals or snacks
- ☐ g Ate higher calorie foods
- ☐ h Got more rest
- ☐ i Ate more junk foods
- ☐ j Ate healthier foods
- ☐ k Used meal supplements *(such as Instant Breakfast, Boost or Ensure)*
- ☐ l Stopped dieting
- ☐ m Exercised less
- ☐ n Other, *Please explain below:* _____
- ☐ o Nothing

90. **During your pregnancy, did anyone tell you that you were gaining too much weight?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 92*

91. **If yes, who told you this?** *(please check all that apply)*

- ☐ a spouse or partner
- ☐ b friend
- ☐ c mother
- ☐ d other family member
- ☐ e doctor
- ☐ f midwife
- ☐ g nurse/nurse practitioner
- ☐ h nutritionist or dietitian
- ☐ i WIC staff
- ☐ j commanding officer

92. **Which of the following things did you do to control your weight during pregnancy?** *(check all that apply)*

- ☐ a Ate less food
- ☐ b Followed a low calorie diet
- ☐ c Skipped meals
- ☐ d Fasted for at least one day
- ☐ e Participated in organized weight loss programs *(example: Weight Watchers, Jenny Craig ,etc.)*
- ☐ f Participated in military-sponsored weight loss programs
- ☐ g Avoided junk foods *(examples: sweet or salty snacks, fast food, candy, etc.)*
- ☐ h Used herbal medications
- ☐ i Hypnosis, biofeedback, etc.
- ☐ j Relaxation, visualization, meditation, or stress reduction techniques
- ☐ k Psychotherapy or behavior modification
- ☐ l Received nutrition counseling from a dietitian or nutritionist
- ☐ m Received nutrition counseling from another health care provider
- ☐ n Smoked cigarettes
- ☐ o Meal replacements *(example: SlimFast)*
- ☐ p Took weight loss pills *(over-the-counter or prescription)*
- ☐ q Took laxatives to lose weight
- ☐ r Took diuretics or water pills
- ☐ s Intentionally vomited after eating
- ☐ t Used low calorie sweeteners *(examples: Equal, Sweet-N-Low, NutraSweet, etc.)*
- ☐ u Drank diet soft drinks
- ☐ v Bought low fat foods *(examples: low-fat salad dressing, low-fat ice-cream or low-fat cookies, etc.)*
- ☐ w Liposuction
- ☐ x Tried to be more physically active
- ☐ y I worried but did nothing
- ☐ z Did nothing

The following questions are about how you are today

93. **In your opinion, how much would you like to weigh?**

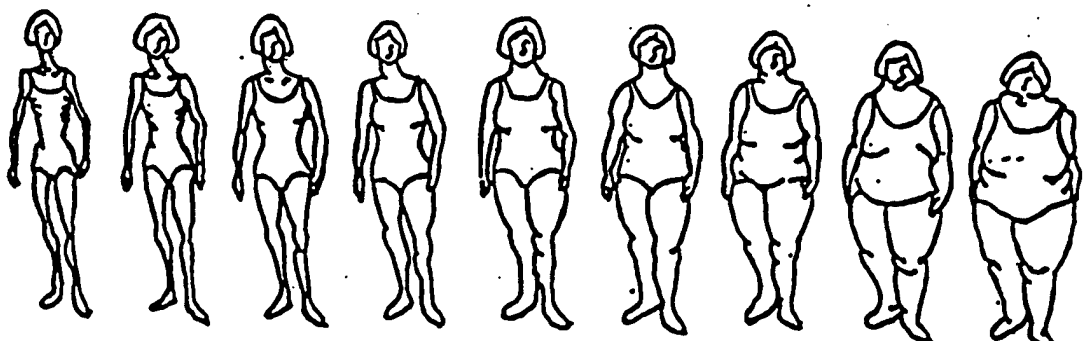
_____ *pounds*

94. **Currently, do you think you are...**

☐ 1	☐ 2	☐ 3	☐ 4
Underweight	just about the right weight	a little overweight	very overweight

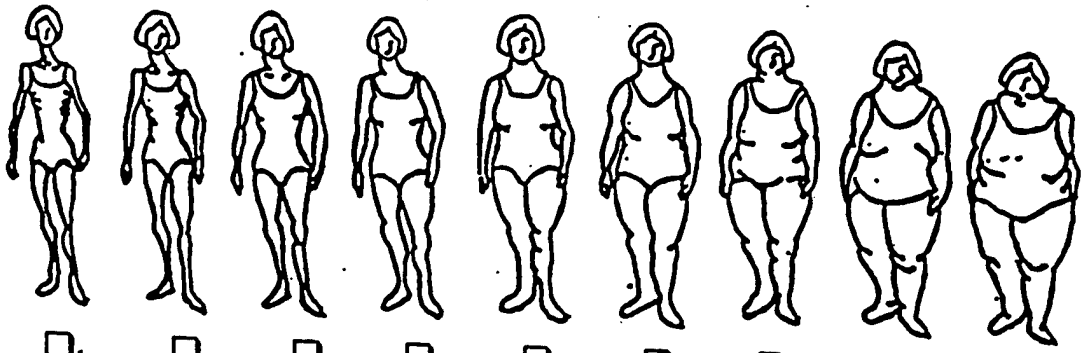
Below are some pictures of women of various sizes. Select the letter of the picture that comes closest to your response.

95. **Today, you look most like:**



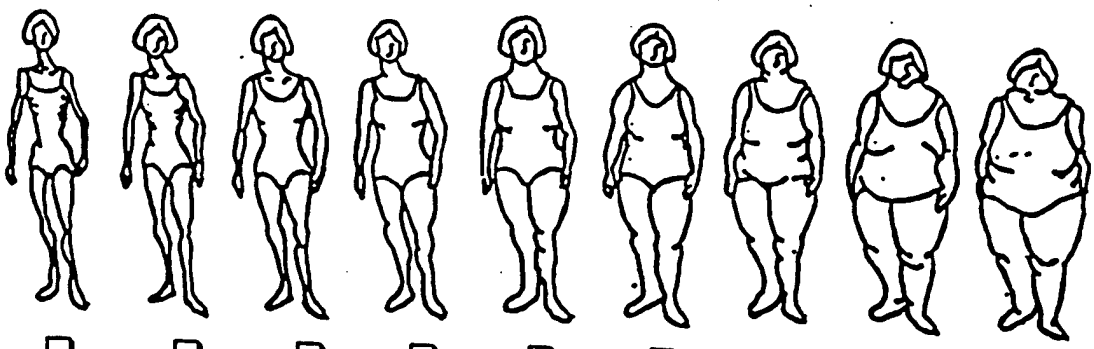
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

96. **You would like it best if you looked like:**



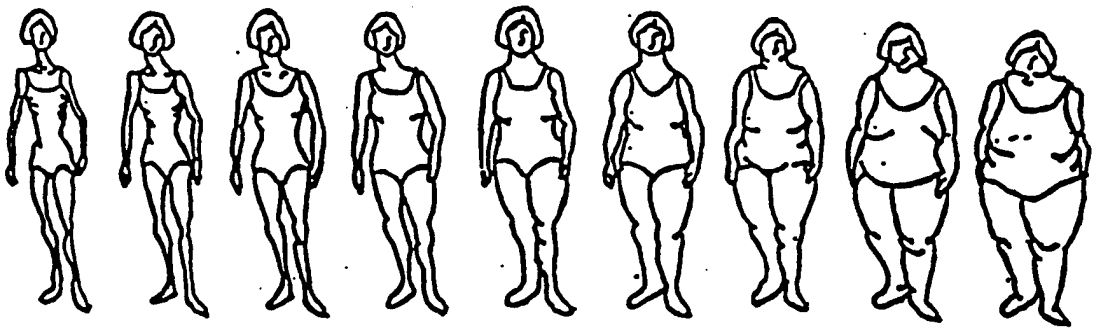
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

97. **Your spouse/partner wishes you looked like:** ☐88 DON'T KNOW ☐99 NOT APPLICABLE



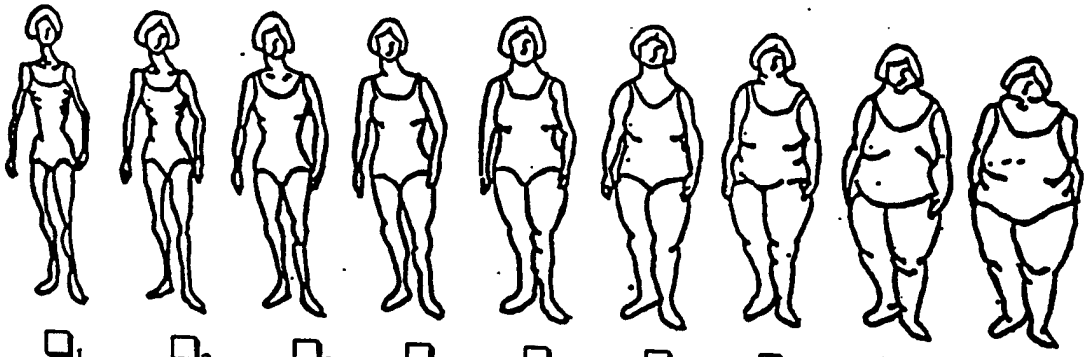
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

98. **Your biological mother usually looks(looked) like:** ☐$_{88}$ DON'T KNOW
☐$_{99}$ NOT APPLICABLE



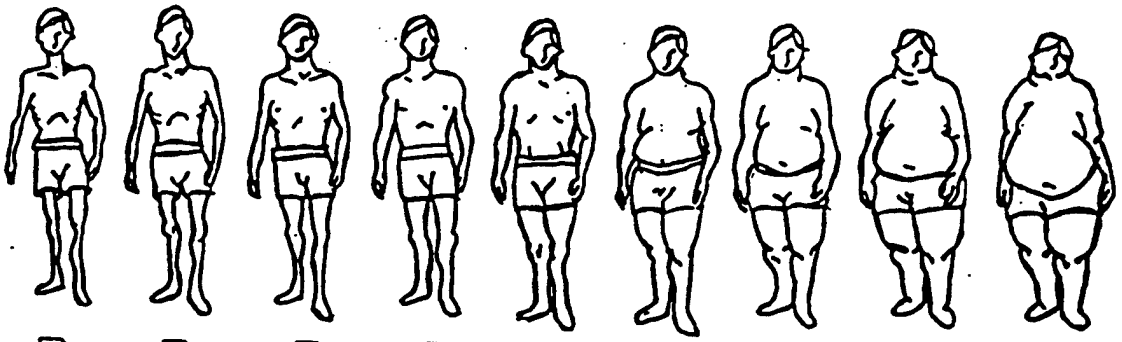
☐$_1$ A ☐$_2$ B ☐$_3$ C ☐$_4$ D ☐$_5$ E ☐$_6$ F ☐$_7$ G ☐$_8$ H ☐$_9$ I

99. **When your biological mother was her <u>heaviest</u>** ***(not including when she was pregnant)*****, she looked like:** ☐$_{88}$ DON'T KNOW
☐$_{99}$ NOT APPLICABLE



☐$_1$ A ☐$_2$ B ☐$_3$ C ☐$_4$ D ☐$_5$ E ☐$_6$ F ☐$_7$ G ☐$_8$ H ☐$_9$ I

100. **Your biological father usually looks(looked) like:** ☐$_{88}$ DON'T KNOW
☐$_{99}$ NOT APPLICABLE



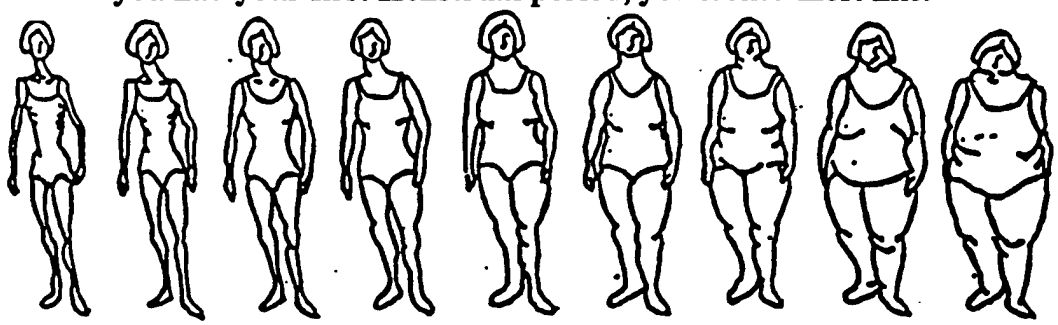
☐$_1$ A ☐$_2$ B ☐$_3$ C ☐$_4$ D ☐$_5$ E ☐$_6$ F ☐$_7$ G ☐$_8$ H ☐$_9$ I

For the following questions, think about when you were younger and a child

101. **How old were you when you had your first menstrual period?** ☐ 88 DON'T KNOW

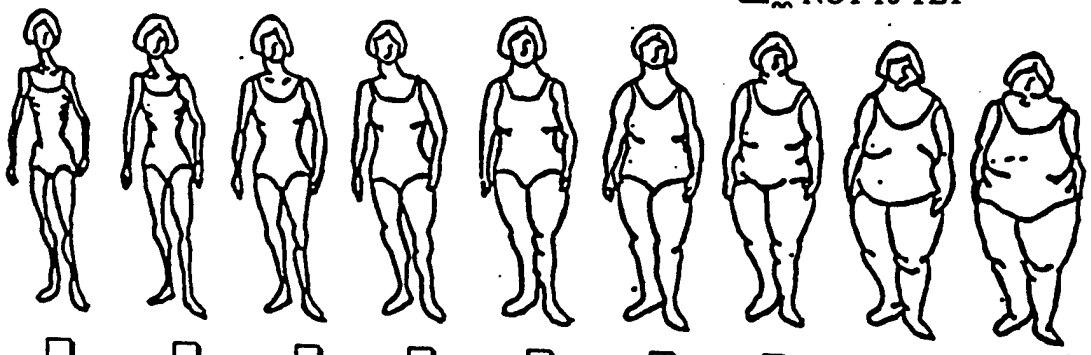
_____ *age of first period*

102. **When you had your first menstrual period, you looked most like:**



☐ 1 A ☐ 2 B ☐ 3 C ☐ 4 D ☐ 5 E ☐ 6 F ☐ 7 G ☐ 8 H ☐ 9 I

103. **When you were 18 years old, you looked most like** ☐ 88 DON'T REMEMBER ☐ 00 NOT 18 YET



☐ 1 A ☐ 2 B ☐ 3 C ☐ 4 D ☐ 5 E ☐ 6 F ☐ 7 G ☐ 8 H ☐ 9 I

104. **Overall, when you were a little girl, were you...**

☐ 1 Underweight ☐ 2 Just about the right weight ☐ 3 A little overweight ☐ 4 Very overweight

105. **Have you smoked at least 100 cigarettes (about 5 packs) in your lifetime?**

☐ 1 Yes

☐ 2 No → *IF NO, GO TO QUESTION 112*

106. **Did you smoke any cigarettes while you were pregnant with this baby?**

☐ 1 Yes

☐ 2 No → *IF NO, GO TO QUESTION 110*

107. **During the <u>first trimester</u> *(0-12 weeks)*, on average, how many cigarettes did you smoke a day?**

First trimester = _____ *cigarettes/day (if none, enter "0")*

108. **During the <u>second trimester</u> *(13-28 weeks)*, on average, how many cigarettes did you smoke a day?**

Second trimester = _____ *cigarettes/day (if none, enter "0")*

109. **During the <u>third trimester</u> *(29 weeks - delivery)*, on average, how many cigarettes did you smoke a day?**

Third trimester = _____ *cigarettes/day (if none, enter "0")*

110. **During the past 30 days, did you smoke any cigarettes?**

☐ 1 Yes

☐ 2 No → *IF NO, GO TO QUESTION 112*

111. **On average, how many cigarettes did you smoke a day?**

_____ *cigarettes/day*

112. **Since your baby's birth, have you drank any alcoholic beverages?** *(An alcoholic beverage includes beer, wine, wine coolers, mixed drinks or hard liquor.)*

☐ 1 Yes

☐ 2 No → *IF NO, GO TO QUESTION 115*

113. **During the past 7 days, how many days did you drink any alcoholic beverages?**

_____ *days/week (if none, enter "0")*

114. **On the days that you drank alcohol, on average how many drinks did you have?** *(One drink is either: a 12 ounce can of beer, a 6 ounce glass of wine, a 12 ounce wine cooler, or an ounce (one shot) of hard liquor, that may or may not be in a mixed drink.)*

_____ *drinks/day*

115. **Would you describe yourself as....***(check all that apply)*

- ☐ a White
- ☐ b Black/African-American
- ☐ c Hispanic
- ☐ d Latina
- ☐ e Mexican
- ☐ f Cuban
- ☐ g Chinese
- ☐ h Japanese
- ☐ i Filipino
- ☐ k Another Asian ethnicity _____
- ☐ l Native American/Alaskan Native
- ☐ m Another group not listed _____

116. **What is the current monthly income, before taxes, for your household? Please include all sources for all family members. Include jobs, social security, retirement income, unemployment payments, WIC** *(Women, Infants and Children)* **etc.**

- ☐ 1 $500/month or less
- ☐ 2 $501 - $1000 / month
- ☐ 3 $1001 - $1500
- ☐ 4 $1501 - $2000
- ☐ 5 $2001 - $2500
- ☐ 6 $2501 - $3000
- ☐ 7 $3001 - $6250
- ☐ 8 More than $6250/month

117. **Were you on WIC when you were pregnant?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 119*

118. **During which trimesters did you use it?**

- ☐ 1 First trimester *(0-12 weeks)*
- ☐ 2 Second trimester *(13-28 weeks)*
- ☐ 3 Third trimester *(29 weeks – delivery)*

119. **Are you currently receiving WIC for....** *(check all that apply)*

- ☐ 1 Your baby
- ☐ 2 Yourself

120. **What is your current marital status?**

- ☐ 1 Single, never married
- ☐ 2 Married
- ☐ 3 Separated or divorced
- ☐ 4 Widowed

121. **<u>If your spouse or partner is in the military,</u> what is his rank?**

_____

☐ 9 NOT APPLICABLE → GO *TO QUESTION 125*

122. **Since your baby was born, has your spouse or partner been on deployment to another location?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO GO TO QUESTION 125*

123. **<u>If your spouse or partner has been deployed,</u> when did he leave?**

_____ / _____
Month *Year*

124. **<u>If your spouse or partner has been deployed,</u> when did he return or when is he expected to return?**

_____ / _____
Month *Year*

125. **How many years of education do you have?**

- ☐ 1 Didn't complete high school
- ☐ 2 Completed high school or GED
- ☐ 3 Vocational or trade school
  a) **How many years of trade school did you complete?** _____
- ☐ 4 College
  b) **How many years of college did you complete?** _____
- ☐ 5 Graduate school

126. **Approximately how tall is the father of your new baby?**

_____*feet* _____*inches* ☐ 88 DON'T KNOW

127. **Approximately how much does the father of your new baby weigh?**

_____*pounds* ☐ 88 DON'T KNOW

128. **Would you describe the father of your baby as**.....*(check all that apply)*

- ☐ a White
- ☐ b Black/African-American
- ☐ c Hispanic
- ☐ d Latina
- ☐ e Mexican
- ☐ f Cuban
- ☐ g Chinese
- ☐ h Japanese
- ☐ i Filipino
- ☐ k Another Asian ethnicity _____
- ☐ l Native American/Alaskan Native
- ☐ m Another group not listed _____
- ☐ n DON'T KNOW

CONTINUE ON NEXT PAGE →

LAST 4 SSN _____ FSCID : 628 _____

TO PROTECT YOUR PRIVACY, THIS PAGE WILL BE SEPARATED FROM THE QUESTIONNAIRE UPON RECEIPT BY ABC STAFF

Would you like a copy of the study results? YES ❑$_1$ NO ❑$_2$

Your Name:

PLEASE COMPLETE YOUR HOME OF RECORD INFORMATION BELOW

Name:	
c/o:	
Street Address:	
City:	
State:	Zip:

ACTIVE DUTY WOMEN CONTINUE BELOW
ALL OTHERS STOP. - Thank You!

ACTIVE DUTY WOMEN ONLY:

My signature below indicates that I did not fill this survey out during working hours as an active personnel.

_____ _____
Signature *Date*

ABC STUDY MEDICAL RECORD ABSTRACTION FORM FSCID: 628 ___ ___ ___ ___ ___

1. ABSTRACTOR'S INITIALS: ___ ___ ___ 2. DATE OF ABSTRACTION: __ __ / __ __ / __ __
M D Y

SECTION I: RECORD OF INPATIENT TREATMENT

PART A: ADMISSION/DISPOSITION

A1. ACTIVE DUTY: Duty ❑1 Home ❑2

PART B: PROCEDURES

B1. METHOD OF DELIVERY:

a. Infant #1 Vaginal ❑1 Cesarean ❑2 Vacuum extraction ❑3 Forceps ❑4

b. Infant #2 Vaginal ❑1 Cesarean ❑2 Vacuum extraction ❑3 Forceps ❑4

PART C: SELECTED ADMINISTRATIVE DATA

C1. MARITAL STATUS:

Married ❑1 Single ❑2 Divorced ❑3 Widowed ❑4 Not reported ❑9

C2. PAY GRADE (Mom): ___ ___ C3. TITLE (Mom): _____

C2a. PAY GRADE (Sponsor) ___ ___ C3a. TITLE (Sponsor) _____

C4. RACE: _____ C5. ETHNICITY: _____

SECTION II: NARRATIVE SUMMARY (FORM #502)

PART D: PRENATAL COURSE

D1. PARITY: a. Gravida ___ b. Para ___

D2. GESTATIONAL AGE: ___ ___ weeks

PART E: DELIVERY NOTE

E1. DELIVERY DATE: ___ ___/___ ___/___ ___
M D Y

E2. SEX:

a. Infant #1 Male ❑1 Female ❑2

b. Infant #2 Male ❑1 Female ❑2

E3. BIRTH WEIGHT:

a. infant #1:___ ___ ___ ___ grams

b. infant #2:___ ___ ___ ___ grams

PART F: DISCHARGE NOTE: F1. POST-DELIVERY HEMATOCRIT: ___ ___ . ___ %

SECTION III: PRENATAL AND PREGNANCY (FORM #533)

PART G: PRENATAL AND PREGNANCY

G1. USUAL WEIGHT: ___ ___ ___ pounds

G2. LAST MENSTRUAL PERIOD: ___ ___ / ___ ___ / ___ ___

G3. PRENATAL WEIGHTS:

	a. **DATE OF VISIT:** (M - D - Y)		b. **WEIGHT:**
1.	___ ___ / ___ ___ / ___ ___	1.	___ ___ ___ • ___ ___ lbs.
2.	___ ___ / ___ ___ / ___ ___	2.	___ ___ ___ • ___ ___ lbs.
3.	___ ___ / ___ ___ / ___ ___	3.	___ ___ ___ • ___ ___ lbs.
4.	___ ___ / ___ ___ / ___ ___	4.	___ ___ ___ • ___ ___ lbs.
5.	___ ___ / ___ ___ / ___ ___	5.	___ ___ ___ • ___ ___ lbs.
6.	___ ___ / ___ ___ / ___ ___	6.	___ ___ ___ • ___ ___ lbs.
7.	___ ___ / ___ ___ / ___ ___	7.	___ ___ ___ • ___ ___ lbs.
8.	___ ___ / ___ ___ / ___ ___	8.	___ ___ ___ • ___ ___ lbs.
9.	___ ___ / ___ ___ / ___ ___	9.	___ ___ ___ • ___ ___ lbs.
10.	___ ___ / ___ ___ / ___ ___	10.	___ ___ ___ • ___ ___ lbs.
11.	___ ___ / ___ ___ / ___ ___	11.	___ ___ ___ • ___ ___ lbs.
12.	___ ___ / ___ ___ / ___ ___	12.	___ ___ ___ • ___ ___ lbs.
13.	___ ___ / ___ ___ / ___ ___	13.	___ ___ ___ • ___ ___ lbs.
14.	___ ___ / ___ ___ / ___ ___	14.	___ ___ ___ • ___ ___ lbs.
15.	___ ___ / ___ ___ / ___ ___	15.	___ ___ ___ • ___ ___ lbs.

G4. TOBACCO: a. none ❑1 former ❑2 during preg. ❑3 b. amount: _____ pks/dy

G5. ALCOHOL USE: no ❑1 during pregnancy ❑2

G6. ANY MEDICAL CONDITIONS: no ❑1 yes ❑2

G7. PAST PREGNANCIES:

a. **YEAR**	b. **DELIVERY METHOD**	c. **COMMENTS**
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____

PART H: DATING CRITERIA

H1. 1ST SONOGRAM: DATE: ___ ___ / ___ ___ / ___ ___ (MM/DD/YY) NONE

H2. WEEKS: ___ ___ H3. DAYS: ___

H4. SONO EDC: ___ ___ / ___ ___ / ___ ___

DATA MANAGEMENT IN SF

Data from SD arrives into SF on Tuesdays
The box is opened and the enrollment folders are checked against the enclosed tally sheet. Each piece of the folder is checked for completeness and FSCID#s are checked on all pieces.

Clinic Questionnaires
Check that the FSCID# is correct. Stamp date received and put into the **Being Batched Drawer.**

Batch into groups of 50 by type and version. Tracking info entered. Qs are then put into the **Ready for Coding Drawer.**

UCB staff codes Qs, then puts them into the **Ready for DE Drawer.**

UCB sends to data entry.

Screener Forms
Check boxes at bottom of screener, indicating the following are in enrollment folders: release, consent, clinic Q, weight. Record visit #.

Check FSCID#, baby's DOB, and mother's name against the database. Make corrections to screener if necessary.

Disposition codes 1, 2, 5, 10, and 11 go to data entry.

Consent Forms
If it is signed by mother, it is sent back to SD.

If it is not signed by mother, we copy it, and send the copy to the mother with a letter and prepaid envelope.

We receive signed consent form from mother, and forward it to SD.

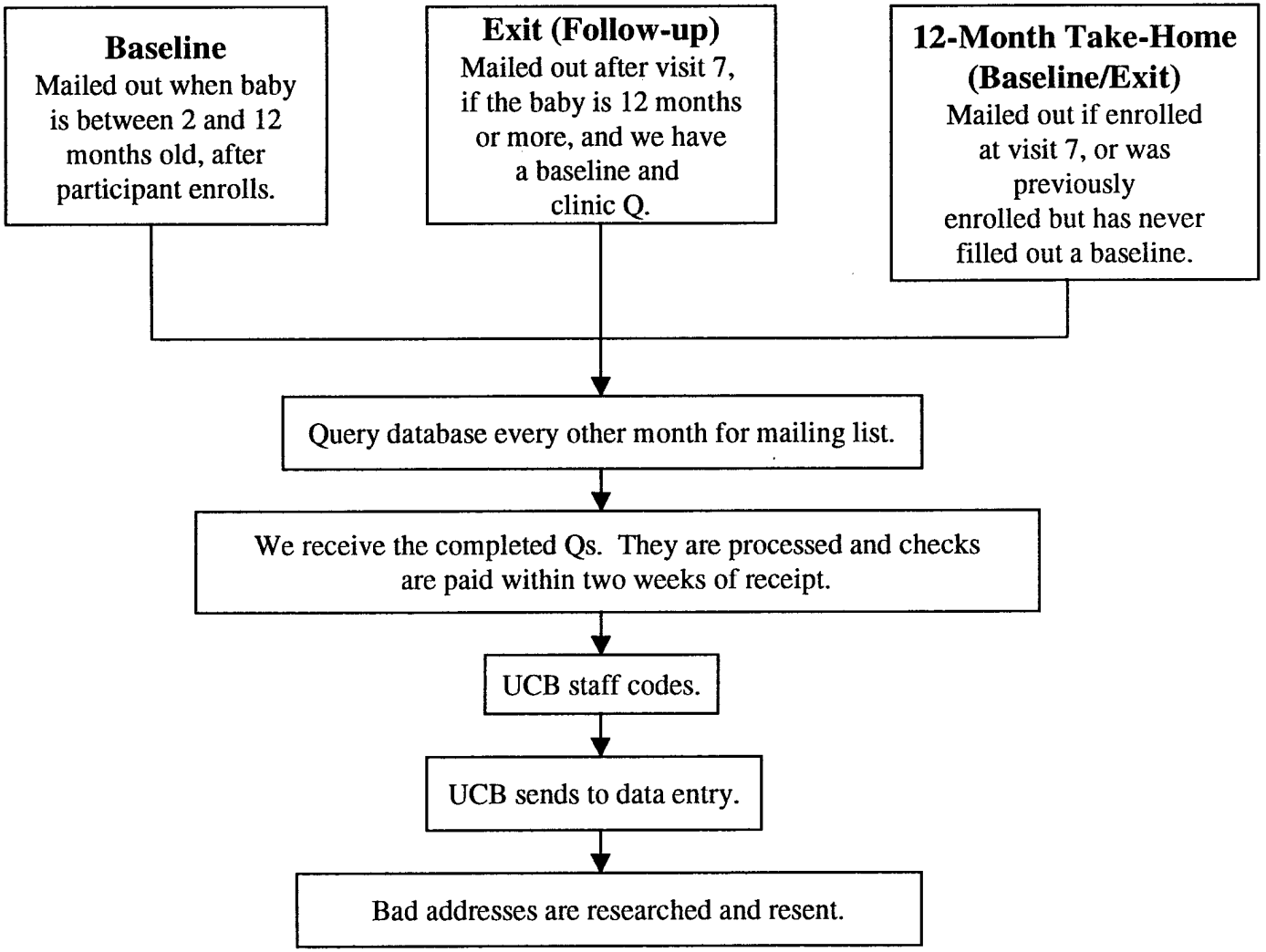
Medical Record Release Forms
Ensure it is the correct form for the participant and that it is signed.

If it is not signed by mother, we copy it, and send the copy to the mother with a letter and prepaid envelope.

We receive signed release form from mother, and file it in SF.

UCB makes copies and processes them.

TAKE-HOME QUESTIONNAIRES



CLINICAL RESEARCH DEPARTMENT
NAVAL MEDICAL CENTER
SAN DIEGO, CALIFORNIA 92134-5000

6500
AVA
27 Oct 98

From: Chairman, Committee for the Protection of Human Subjects
To: CDR Martin McCaffrey and Roslynn Lindemann, RN

Subj: APPROVAL OF MODIFIED CONSENT FORM

Encl: (1) Approved consent form for CIP #S-96-078

1. The informed consent document for CIP #S-96-078, "Postpartum Maternal Weight Changes: Implications for Military Women," dated 27 Oct 98 is approved.

2. Approval of the consent form will be documented in the combined monthly minutes of the Scientific Review Committee and the Committee for the Protection of Human Subjects.

3. Use only this consent form with the stamped seal for CPHS which is initialed and dated by the Chairman.

Date 29 Oct 98

K. D. GUBLER
Captain, Medical Corps
United States Navy
Chairman, Committee for the
Protection of Human Subjects

NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

CONSENT BY A SUBJECT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION (RESEARCH) STUDY

1. _____, have been asked voluntarily to participate in a research project titled, **"Postpartum Maternal Weight Changes: Implications for Military Women"** also known as **"After the Baby Comes: The ABC Study,"** being conducted at the Medical Center, San Diego by medical researchers from the Departments of OB/GYN and Pediatrics in collaboration with the School of Public Health at the University of California at Berkeley.

2. The objectives or purposes of this research are to describe how maternal lifestyles, body weight and fitness change in active duty military women and in family members of active duty servicemen during the first year after they each give birth to a baby. We are also studying how the amount and pattern of a mother's weight gain during pregnancy affects the size and health of the baby.

3. I understand that my participation in this research project will be one visit today and every time I bring my baby in for well baby health visits (approximately 7 visits). I may participate today even if I know that I will not be able to participate in the future.

4. The procedures for this project include the following:

a. If I choose to participate in this study today, study staff will:

(1) weigh me on a scale in the clinic and measure my height;

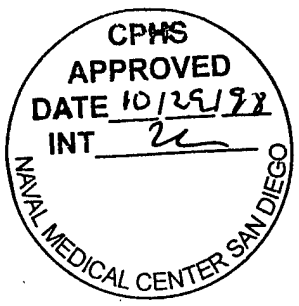
(2) ask me to complete a short questionnaire (approximately 5-10 minutes to fill out);

(3) if my baby is at least 2 months old, ask me to complete a take home questionnaire providing information about my current lifestyle (for example, infant feeding, work, diet and exercise) and my views about diet and weight. Study staff

Subject's Initials: _____

CPHS/IRB Approval Stamp/Seal Required

Revised 27 Oct 98



estimate it will take about 20 minutes to complete this questionnaire;

(4) ask me to sign a form giving the study staff permission to examine my prenatal medical records, and if I am on active duty, my Physical Readiness Test (PRT) records. Study staff will only examine and record information in my prenatal record that is directly related to this study (for example, military status, my weight gain in pregnancy, pregnancy complications and infant size). The PRT records will be examined for information on my weight and PRT scores for the last test I took prior to becoming pregnant and for the first test I took or will take after the baby is born; and

(5) study staff will also request my social security number so that they can examine information on my baby's birth certificate. This will allow them to understand who participated in their study compared to all women who had babies in California delivered during the same year.

b. Once I enroll in this study, study staff will meet me every time I bring my baby in for regularly scheduled well-care visits. Study staff will:

(1) weigh me on a scale in the clinic;

(2) ask me to complete a short questionnaire (approximately 5-10 minutes to fill out); and

(3) ask me to fill out a second take-home 20 minute questionnaire at my baby's 12 month visit.

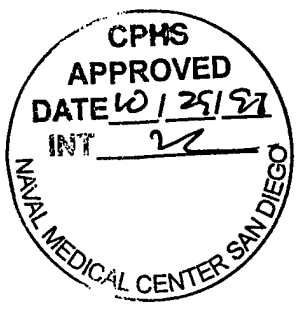
Even if I plan to move away or miss future visits, I may still participate today.

I understand that I will be compensated $10.00 when I fill out the initial take-home (20 minute) questionnaire and another $10.00 when I complete the second take-home questionnaire when my baby is 12 months old. However, in order to be compensated, I must fill out the questionnaires during my off-duty time.

c. Study staff may recontact me to verify or clarify some of my answers on the questionnaires. My responses will be entered

Subject's Initials: _____

CPHS/IRB Approval Stamp/Seal Required



Revised 27 Oct 98

into a database which will be used to gain important knowledge about the health of mothers and their infants.

5. A total of 4000 subjects are expected to participate in this study from the Naval Medical Center, San Diego.

6. The risks or discomforts to me while participating in this study are very small. There is a possibility that some of the questions could disturb me. I have the right to skip any questions which I do not wish to answer. The only other known discomfort from my participation in this study is the additional time it will take me to answer the questions and participate in this research study.

7. I understand that my participation in this research project may or may not be of direct benefit to me personally. However, the results of this study may help the investigator gain important knowledge about prenatal weight gain and infant health, and postpartum weight changes in new mothers that may benefit pregnant women and new mothers in the future.

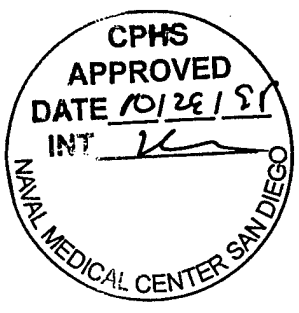
8. I understand that researchers do not expect any of the information collected by this research project will be entered into my medical records. All data and medical information obtained about me as an individual will be considered privileged and held in confidence; I will not be identified in any presentation or publication of the results.

a. Research staff will take every precaution to preserve the confidentiality of the research information. All questionnaires will be stored in locked cabinets. Pre-assigned code numbers will be included in the body of each questionnaire as well as on a separate page on which identifying information is collected. After I complete the questionnaire and it is assessed by study staff for completeness, the page with subject identifiers and code numbers will be immediately detached from the coded questionnaire. Thus, questionnaire data will be entirely unidentifiable. Identifying information will be stored in a separate data file, and a linking number will be required to connect the identifying information with subject data.

b. Abstraction of records will be accomplished using a laptop computer by trained project staff who will sign a confidentiality agreement and examine only information specifically required by the study. After data from various sources is merged, all

Subject's Initials: _____

CPHS/IRB Approval Stamp/Seal Required



Revised 27 Oct 98

identifying information will be purged, so that the final analytic data set contains no identifying information.

c. I also understand that complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on my health may be required to be reported to appropriate medical or command authorities. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

9. If I suffer any injury directly related to my participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego or at another closer military medical treatment facility, if applicable. I must be eligible for DoD medical care to be eligible for this study. I understand that although no financial compensation is available, any injury resulting from my participation in this study will be evaluated and treated in keeping with the benefits or care to which I am entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

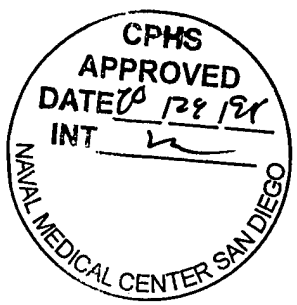
10. If I have any questions regarding this research study, I may contact **CDR Martin McCaffrey**, Department of Pediatrics, NMCSD at **(619) 532-8927** or **Roslynn Lindemann**, Department of Obstetrics and Gynecology, NMCSD at **(619) 532-8910**. I may also call (collect) **Professor Barbara Abrams**, Associate Professor, UC Berkeley at **(510) 642-4216**. If I have any questions about my rights as an individual while participating in a research study at the Naval Medical Center, San Diego, I may contact **CAPT K. Dean Gubler**, MC, USN, Chairman, Committee for the Protection of Human Subjects at **(619) 532-8125** or **CAPT F. W. Hall**, MC, USN , Head, Clinical Research Department, at **(619) 532-8127**. If I believe that I have been injured as a result of my participation in this research study, I may contact **CDR Lynn McNees**, JAGC, USN, at the Naval Medical Center, San Diego, Legal Department at **(619) 532-6475.**

11. I understand that my participation in this project is entirely voluntary and that my decision not to participate will involve no penalty or loss of benefits to which I am entitled under applicable regulations. If I choose to participate, I am free to ask questions or to withdraw from the study at any time. If I should decide to withdraw from the research project, I will notify **CDR Martin McCaffrey at (619) 532-8927 or Roslynn**

Subject's Initials: _____

CPHS/IRB Approval Stamp/Seal Required

Revised 27 Oct 98



Lindeman, RN, at (619) 532-8910 or **Professor Barbara Abrams at (510) 642-4216.** My withdrawal will involve no prejudice to my future health care or any loss of rights or benefits to which I am otherwise entitled. Any new significant finding developed during the course of this study which might affect my willingness to continue participation will be communicated to me.

12. The investigator may terminate my participation in this study at this investigator's discretion.

13. I have been informed that there will not be additional costs to me if I choose to participate in this project.

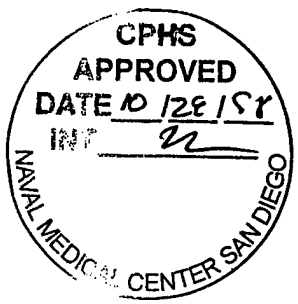
14. I understand that I am making a decision whether or not to participate in the research project described in the preceding sections subject to the conditions of participation described above. My signature indicates that I have decided to participate, having read and understood the information presented above and having been given the opportunity to ask any questions that I might have about the research study or my participation in the study. Further, my signature indicates that I have been provided with a copy of this consent document and a copy of a document titled, "Experimental Subject's Bill of Rights."

15. I have been informed that I will be provided with a copy of the results of this study by checking this box. ☐

SIGNATURES AND DATE SIGNED: PRINTED/TYPED IDENTIFICATION:

Patient/Subject Date	Name/Status/Sponsor's SSN
Witness Date	Name/Grade or Rank/SSN
Researcher/Investigator Date	M^c^Caffrey CJR 041-68-8611 Name/Grade or Rank/SSN

CPHS/IRB Approval Stamp/Seal Required



Revised 27 Oct 98

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Department of the Navy, the Department of Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center San Diego and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. I have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

SIGNATURES AND **DATE** SIGNED: **PRINTED** OR **TYPED IDENTIFICATION:**

Patient / Subject (Date) (if Applicable)	Name / Status / Sponsor's SSN
Parent / Guardian (Date) (if Applicable)	Name / Status / SSN
Witness (Date)	Name / Grade or Rank / SSN

EXPERIMENTAL SUBJECTS BILL OF RIGHTS (CA)

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment;

2. Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used;

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment;

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable;

5. Be given a disclosure of appropriate alternative procedures, drugs, or devices that might be advantageous to the subject and their relative risks and benefits;

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if any complications should arise;

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved;

8. Be instructed that the consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice;

9. Be given a copy of a signed and dated written consent form when one is required;

10. Be given the opportunity to decide to consent or not consent to medical experiment without intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision; and

11. Be assured that the subject's confidentiality will be preserved and his/her name will not be released without his/her permission.

Any questions regarding this research study should be directed to the principal investigator or associate investigators. Information is available from the Chairman, Committee for the Protection of Human Subjects, established for the protection of volunteers in research projects at this facility by calling (619) 532-8125 or writing the Chairman, Committee for the Protection of Human Subjects at Naval Medical Center, Clinical Investigation Department (Code AVA), San Diego, CA 92134-5000

Telephone Interview Protocol

1. Get faxed Master Lists from San Diego.
2. Look up mom by FSC ID# in Berkeley Participant Tracking Database and print her Participant Profile.

- Mark the hard copy of this Participant Profile for each mom you are calling.
- Be sure to do this prior to making any calls.
- Mark the Participant Profile in the following way:

➢ If the baby is 2-9 months old and there is no date for a baseline questionnaire received, highlight the baseline box

➢ If the baby is 12-15 months of age and no baseline questionnaire has been received, highlight the combo box

➢ If baby's age is 12-15 months and we have received a baseline questionnaire but there is no date for a exit questionnaire received, highlight the exit box

➢ If there is a "6" in the MRA status box, their release has expired - highlight the MRA box

- All points that are highlighted are topics that you are going to discuss with the Mom.

3. Call moms on the list and call moms that we were previously unable to reach

<u>If no answer or machine:</u>

➢ call back at the end of shift,
➢ if there is still no answer leave for the next shift to call
➢ (day for night, night for day)

<u>If moms is not home:</u>

➢ Ask when is a good time to call back
➢ call her back at that time

or

➢ leave for the next shift to call

<u>If mom is reached:</u>

➢ use the script
➢ introduce yourself
➢ ask weight
➢ ask truncated clinic questionnaire questions

➢ Be sure to reference your Participant Profile and discuss all highlighted points.

- If Baseline or Exit questionnaire is missing, tell them they will be receiving it in the mail and will receive $10 when they mail it back.

- If we need a new signature on a medical release form, ask if they will sign a new one for us
- have mom either mail Q and medical release back to us or return them in the clinic and tell her she will get a purple barney type dinosaur when she does
- If she returns it in the clinic then she can get the incentive at that time

- If she mails it back, tell her we will put her name on a list and she can ask for one the next time she is in the clinic

<u>In the clinic:</u>

- When a mom mentions a purple dinosaur this will tip recruiter off to the need to make sure they get her weight.

- Mom will also sign on a clip board when she gets the incentive.

4. After you are done with all your calls, fill in the log so that we can determine the success of the calls.
5. Send a letter to each participant reached enumerating all of the points discussed during the call.
6. Be sure to reference the Participant Profile

- Mom's weight recorded
- Phone Interview form completed
- Clinic questionnaire - incentive when completed and returned

- Baseline questionnaire - $10 when completed and returned

- Exit questionnaire - $10 when completed and returned

- Combo BL/Exit questionnaire - $10 completed and returned

- MRA - if new signature is needed on release form, include that (no incentive)
- include a SASE

Telephone Interview Script

Hi may I please speak with **<<Mom's name>>.** Hi this is **<<Caller's Name>>**, with the ABC Study.

Do you have a couple of minutes?

Great...At **<<Baby's Name>>** last clinic appointment we missed getting your weight, and I had some quick questions.

Can I verify your address? Is it still **<<read off of Participant Profile>>?**

<<Ask Mom her weight. After you record this information on the telephone interview form, ask her the rest of the questions on the form>>.

To thank you for your time I wanted to let you know that we have a stuffed purple Barney-like toy for you and **<<Baby's>>**.

Did you get a **<<color>>** survey we mailed to you in the past couple of weeks?

If YES

Great! Can you please fill it out and get it back to us? There was an envelope to send it back, right? That way we can send your $10 check right away.

If NO

Oh, then I'm going to send one to you to make sure you get it—okay? Could you just fill it out and send it back to us.

If by chance you get two, just fill out one and return it and you can throw the other one away.

Thanks so much. Have a great _____.

Telephone Interview

Date of Interview **time**

FSCID 6280_____ interviwer initials _____ ____/____/____ _____

1. **Can you step on a scale and let us know your weight?**

   _____ lbs

2. **Are you currently breastfeeding your baby?**

   ☐ 1 Yes
   ☐ 2 No

3. **Is your baby getting any infant formula?**

   ☐ 1 Yes
   ☐ 2 No

4. **During the past 7 days, did you work at a job or as a volunteer?**

   ☐ 1 Yes
   ☐ 2 No

   How many hours did you work? _____

5. **During the past 7 days, did you spend time at school?**

   ☐ 1 Yes
   ☐ 2 No

   How many hours did you spend going to school? _____

6. **During the past 7 days, how many times did you participate in any sports or exercise?**

   Number of times in 7 days = _____ times

7. **Have you had your menstrual period since your baby was born?**

   ☐ 1 Yes
   ☐ 2 No

<u>If you have had your period</u>, what was the first day of your last menstrual period?

_____ / _____ / _____
Month *Day* *Year*

8. **During the past 7 days, did you do anything to control your weight, or to help you lose weight?** *(check all that apply)*

- ☐ a Ate less food
- ☐ b Followed a low calorie diet
- ☐ c Skipped meals
- ☐ d Fasted for at least one day
- ☐ e Participated in organized weight loss programs *(example: Weight Watchers, Jenny Craig ,etc)*
- ☐ f Participated in military-sponsored weight loss programs
- ☐ g Avoided junk foods *(examples: sweet or salty snacks, fast food, candy, etc.)*
- ☐ h Used herbal medications
- ☐ i Hypnosis, biofeedback, etc.
- ☐ j Relaxation, visualization, meditation, or stress reduction techniques
- ☐ k Psychotherapy or behavior modification
- ☐ l Received nutrition counseling from a dietitian or nutritionist
- ☐ m Received nutrition counseling from <u>another</u> health care provider
- ☐ n Smoked cigarettes
- ☐ o Meal replacements *(example: SlimFast)*
- ☐ p Took weight loss pills *(over-the-counter or prescription)*
- ☐ q Took laxatives to lose weight
- ☐ r Took diuretics or water pills
- ☐ s Intentionally vomited after eating
- ☐ t Used low calorie sweeteners *(examples: Equal, Sweet-N-Low, NutraSweet, etc.)*
- ☐ u Drank diet soft drinks
- ☐ v Bought low fat foods *(examples: low-fat salad dressing, low-fat ice-cream or low-fat cookies, etc)*
- ☐ w Liposuction
- ☐ x Tried to be more physically active
- ☐ y I worried but did nothing
- ☐ z Did nothing